PATENTED MEDICINE PRICES REVIEW BOARD

**IN THE MATTER OF the *Patent Act*,
R.S.C., 1985, c. P-4, as amended**

**AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. ("Respondent")
and the medicine "Soliris"**

NOTICE OF MOTION

(REQUEST FOR PARTICULARS, CROSS-EXAMINATION OF ERIC LUN, and DIRECTIONS RE: MOTION TO STRIKE PASSAGES OF PROVINCIAL MINISTERS'AMENDED APPEARANCE)

RESPONDENT, ALEXION Pharmaceuticals Inc. ("Respondent" or "Alexion"), will make a motion to the Board at the Pre-Hearing Conference currently scheduled for 22, 23, and 24 June 2015, at the Board's offices in Ottawa.

THE MOTION IS FOR:

1. An Order that Board Staff deliver Alexion particulars of all allegations in the Statement of Allegations ("Allegations") including:

   (a) Under paragraph 15 of the Allegations, details of and concerning all sources used by Board Staff in calculating international prices, and any calculations used, made, or considered by Board Staff in determining all international prices and foreign currency exchange rates upon which allegations of excessive pricing under the Highest International Price Comparison ("HIPC") test are based;

   (b) Under paragraph 16 of the Allegations, particulars of any documents relating to calculations used, made, or considered by Board Staff in comparing Canadian and international prices, or otherwise relevant to the allegation that Alexion was selling Soliris in Canada at the "highest international price" in contravention of the HIPC test;

(c) Pursuant to paragraph 17, particulars of any allegation that the Canadian price of Soliris was higher than the price in the US and, if so, how that allegation is relevant to the HIPC test;

(d) Particulars concerning the calculation of each number found in the table following subparagraph 30(a), including details as to how the calculations were derived (such as why the increase in N-NEAP following 2012 does not follow the HIPC test);

(e) Particulars concerning the calculation of the "cumulative excess revenues" claimed in subparagraph 30(d); and

(f) Particulars of any reason other than alleged failure of the HIPC test that Board Staff relies upon to allege that the price of Soliris is "excessive", including the relationship of any such other reason to the factors specified in subsection 85(1) of the *Patent Act* or the Guidelines. Alternatively, confirmation by Board Staff that there is no reason other than alleged failure of the HIPC test for asserting that the price of Soliris is excessive under the *Patent Act* or the Guidelines.

2. An Order under Rule 26(b) of the *Patented Medicine Prices Review Board Rules* ("Rules"), granting leave to cross-examine Eric Lun on his Affidavit sworn 1 April 2015 ("Lun Affidavit");

3. An Order scheduling a further motion for an order striking out irrelevant portions of the Amended Notice of Appearance filed by the provincial Health Ministers ("Ministers' Amended Appearance") following completion of Mr. Lun's cross-examination;

4. An order extending the date for Alexion to formally reply to the Ministers' Amended Appearance until after Mr. Lun has been cross-examined and the motion to strike out irrelevant portions of the Ministers' Amended Appearance has been heard and decided; and

5. An order permitting Alexion to file a further or amended response following delivery of particulars delivered by Board Staff.

THE GROUNDS FOR THE MOTION ARE:

6. On 20 January 2015, the Board issued its Notice of Hearing ("Notice") and Allegations relating to Alexion and the medicine Soliris. The Notice stated that the "material facts relied upon by Board Staff" were described within the Allegations.

7. The principal assertion in the Allegations is that Alexion has sold Soliris to Canadians "at the highest international price among the comparator countries" listed in the Board's 2010 Compendium of Guidelines, Policies, and Procedures ("Guidelines"). The remedy requested is that Alexion be ordered to "stop selling Soliris at an excessive price" and to disgorge revenues Alexion "has generated from the sale of Soliris at an excessive price."

8. Paragraphs 14 through 21 of the Allegations describe an investigation conducted by Board Staff based upon the HIPC test. The sole theory upon which the allegation of excessive pricing is based relates to application of the HIPC test. There is no allegation that any test other than the HIPC is applicable. The HIPC test presumably applies the statutory factor found in paragraph 85(1)(c) of the *Patent Act* ("the prices at which the medicine...[has] been sold in countries other than Canada") and is only factor implicated or allegedly contravened.

9. Copies of Board Staff's documents, including the Notice and Allegations, were also provided to the Ministers of Health of the various Provinces and Territories ("Ministers"). The Ministers were directed to deliver a Notice of Appearance by 9 February 2015.

10. On 12 February 2015, counsel for Alexion (Gowlings) wrote to Board Staff's counsel, (Perley-Robertson) confirming an agreement, subject to approval of the Hearing Panel, to modify the schedule for delivery of Alexion's Response, Board Staff's Reply, and the first case conference. The 12 February 2015 letter from Gowlings to Perley-Robertson also contained a request for particulars and disclosure of documents relating to Board Staff's calculations "concerning the impact of exchange rates on pricing of Soliris in the comparator countries listed in the Schedule to the *Patented Medicines Regulations*" and the "impact of exchange rates under the Price Comparison test."

11. In a letter dated 20 February 2015, Board Staff's counsel refused to provide particulars. Board Staff did indicate that documents would be delivered "within a reasonable time

frame after the parties exchange pleadings". To date, no documents have been produced by Board Staff.

12. Alexion filed its Response on 9 March 2015 consistent with the Hearing Panel's First Scheduling Order. The Response notes that the Introductory Maximum Non-Excessive ("MNE") for Soliris approved by Board Staff, $223.21, has not increased since Soliris was introduced to the Canadian market in 2009. The Response further notes that Alexion has foregone any increases in price based on the Consumer Price Index ("CPI"), meaning that the price of Soliris has actually decreased in Canada in relative terms since the medicine was first introduced to the Canadian market in June 2009. Indeed, as the Response notes, the allegation of "excessive" pricing under the HIPC is not based on actual price increases for Soliris in Canada or price decreases for Soliris in the comparator countries listed in the Guidelines: rather, the allegation is based solely upon fluctuations in the value of international currencies compared to the Canadian dollar. In sum, Alexion asserts in the Response that Board Staff are effectively comparing the relative value of currencies of various jurisdictions rather than the actual prices of Soliris in Canada and the comparator countries.

13. On 9 March 2015, the Minister of Health for British Columbia ("BC Minister") filed an appearance on behalf of the BC Minister and the Minister of Health for Manitoba ("Ministers' Appearance"). The Ministers' Appearance stated that the Ministers intended "to rely upon the material facts set out in", and the documents appended to, the Allegations. The Ministers' Appearance also made reference to an "Affidavit of Eric Lun which will be filed at a later date" and "any documents submitted by a participant to the hearing." There was no suggestion in the Ministers' Appearance that the Ministers would be referring to evidence or issues different from application of the HIPC issue mentioned in the Allegations.

14. On 17 March 2015, counsel for the BC Minister of Health delivered correspondence detailing further issues they intended to rely upon in an Amended Appearance. On 20 March 2015, Alexion delivered correspondence objecting to the proposed Amendment on the grounds that it was irrelevant to the HIPC allegations referred to in the Allegations. The Board disregarded the objection.

15. On 2 April 2015, counsel for the BC Minister of Health filed the Ministers' Amended Notice dated 13 March 2015, together with an affidavit of Eric Lun sworn 1 April 2015. The Ministers' Amended Notice was also filed on behalf of the Ministers of Health of Ontario and Newfoundland and Labrador.

16. The allegations and facts provided in the Ministers' Amended Notice and the Lun Affidavit bear no relationship to allegations made by Board Staff in the Allegations. In certain respects, the Ministers' allegations contradict those of Board Staff. In particular, Board Staff allege that the price of Soliris failed the HIPC test found in the Guidelines—which provides that the price of a drug in Canada cannot be higher than the highest "international price" among the 'basket' of comparator countries defined in the Guidelines. The remedy in an HIPC case is to request a price reduction to the highest average price and require a patentee to pay the difference between the actual price and the "non-excessive average price" (the "N-NEAP). The Ministers' Amended Notice, however, requests (in paragraph 1) an order that Alexion be required to "...reduce the price of Soliris to a price that does not exceed the lowest price among all comparator countries". Application of the HIPC test uses the "highest" and not the "lowest" price.

17. Moreover, the Ministers' Notice relies on the following categories of material fact derived from the Lun Affidavit:

    (a) the process used by public drug plans to review medicines like Soliris for potential reimbursement;

    (b) the cost of Soliris in comparison to other publicly-funded medicines;

    (c) the importance of the public list price of a medicine in relation to negotiations between provincial governments and suppliers in relation to other reimbursement policies; and

    (d) recommendations made by the Common Drug Review in relation to reimbursement of Soliris by public drug plans.

18. These "concerns" relating to "the pricing of Soliris" raised by the BC Minister bear no relation to the investigation conducted by Board Staff or the sole issue to be determined by the Hearing Panel—whether Alexion's Canadian pricing fails the HIPC test.

19. The proposed material facts articulated in the Ministers' Amended Appearance have nothing to do with comparisons of the price of Soliris in Canada with prices in countries where the medication is sold outside Canada. Indeed, for purposes of this proceeding the Common Drug Review, review procedures of public drug plans, cost of Soliris compared with other publicly-funded medicines in Canada, and public list prices and reimbursement policies have, on their face, no relevance to any of the applicable factors set out in subsection 85 (1) referred to in the Allegations.

20. On 10 April 2015, Board Staff filed a Reply ("Board Reply"). In the Reply, Board Staff stated in paragraph 6 that they were not alleging that the price of Soliris is excessive due to changes in exchange rates. Furthermore, in paragraph 5, Board Staff denied that the introductory price of Soliris in 2009 was "non-excessive". Finally, despite the changes in legal theory raised in the Reply, in paragraph 7 Board Staff also denied that any further particulars of its Allegations were necessary.

21. In correspondence dated 16 April 2015, Alexion objected to alteration or expansion of the issues as stated in Board Staff's Reply.

22. In correspondence to the Board dated 23 April 2015, Board Staff repeated the contradictory assertion that the essential allegations were not about impact of foreign exchange rates, but that "based on the factors under section 85 of the *Patent Act* ... Alexion has been selling Soliris at a price that is excessive since 2012". Moreover, Board Staff disagreed with Alexion's assertion that the facts and allegations made in the Ministers' Appearance were irrelevant. Finally, Board Staff asserted that particulars were moot, given that Alexion had already filed a responsive pleading.

23. In correspondence dated 27 April 2015, Alexion asserted it was entitled to know the case to be met. Furthermore, Alexion pointed out that in the context of this proceeding,

Board Staff have a duty of procedural fairness requiring disclosure of important information underlying their allegations. Alexion repeated its demand for particulars, which has become even more important now that Board Staff are shifting their case theory from contravention of the HIPC test to general and unspecified allegations of excessive pricing without reference to particular factors in s. 85 of the *Patent Act* or provisions of the Guidelines.

24. On 29 April 2015, a Case Management Conference was held to schedule various matters. The Board issued the following Order on 1 May 2015:

(a) Pre-hearing conference to be held 22, 23, and 24 June, 2015;

(b) Materials to be filed 15 May 2015;

(c) Responding materials to be filed 29 May,2015;

(d) Reply materials to be filed 5 June 2015; and

(e) Cross-examinations to be filed 17 June 2015.

25. In the relief it seeks in these motions, Alexion requests what it has asked for since this proceeding was commenced: sufficient information, preferably in one set of allegations, to know the case it has to meet. The particulars are required so that Alexion can meaningfully prepare its case before the Board. It is fallacious to assert, as Board Staff does, that Alexion already has sufficient particulars. Board Staff's position leaves Alexion guessing at Board Staff's case. Board Staff's approach flagrantly violates the most basic notions of procedural fairness in administrative proceedings.

26. In the Allegations, Board Staff claimed that the sole reason for the allegation of excessive pricing was an alleged failure of the HIPC test. The only other facts alleged, for example in paragraphs 5 and 9 that Soliris was expensive, are background in nature.

The allegation in paragraph 17 that the price of Alexion was "appreciably higher" in Canada than in the US is irrelevant in the analysis of any of the tests under the *Patent Act* or the Guidelines.

27. On the facts as alleged, the only reason it could be asserted Soliris failed the HIPC test since 2012 is that foreign currency rates have fluctuated. The actual prices of Soliris, in Canada and comparator countries, have not changed and, in fact, have generally declined because no price increases have been sought to account for inflation.

28. In their various filings and correspondence, Board Staff have adamantly refused to confirm that the only issue before the Board is the impact of fluctuating international currency exchange rates beginning in 2012. Indeed, Board Staff have confused the process by denying that foreign currency rates are at issue and raising additional issues, including a suggestion that the introductory price of Soliriswas excessive when in fact it was only very slightly above the "non-excessive price" (approximately 0.7%); this "excess" was more than offset, in the Board Staff's calculations, by alleged price "decreases" in 2010 and 2011 (caused once again by currency fluctuations). Board Staff have not alleged that the price of Soliris was "excessive" in 2010 or 2011.

29. Moreover, although challenged, Board Staff have expressed their agreement with the Ministers' Amended Appearance but refused to state how the additional allegations made by the Ministers are relevant to s. 85(1) of the *Patent Act*, the Guidelines, or the Board's determination.

30. Without the relief it is seeking, Alexion cannot meaningfully and effectively prepare its case. Alexion is left to guess whether Board Staff intend to restrict their case to the narrow issue of the alleged failure of the HIPC test (which inevitably raises the issue of the impact of foreign currency fluctuations), or whether the case will also include the

undefined and unfocussed allegations of the Ministers, or even some third possibility, as yet undefined.

31. Alexion seeks to resolve all issues expeditiously and in a manner that is cost-effective. As matters stand, Alexion is prejudiced because it does not know the case it has to meet. In contrast, there is no prejudice to Board Staff particularizing their allegations so that Alexion and the Hearing Panel itself fully appreciate and understand the allegations, which will frame the evidence, both fact and expert, that the parties will present.

32. The remainder of the relief sought relates to the Ministers' allegations. . Alexion seeks to have most of these allegations struck out as irrelevant. As currently framed, the hearing deals with the narrow issue of how the Board should treat fluctuations in international exchange rates when considering the HIPC test. The Ministers' allegations are unfocussed general complaints about the price of Soliris and have the potential to convert the hearing into a broad inquiry into procurement of patented medicines by public entities across Canada. The Board's purpose is to determine allegations within the statutory scheme in the *Patent Act* and, if applicable, the Guidelines. The Board is not a commission of inquiry into the price of patented medicines in Canada.

33. The cross-examination of Mr. Lun is a necessary predicate to bringing a motion to strike portions of the Ministers' allegations. It is anticipated that questions posed to Mr. Lun will establish that the impugned portions of the Amended Ministers' Appearance are irrelevant to the Panel's determinations based on the *Patent Act* and Guidelines. The motion to strike cannot be argued without providing Alexion an opportunity to test the evidence in Mr. Lun's affidavit.

34. The relief sought in the motions will move the matter forward. The hearing before the Panel will be focussed on particularized allegations permitting each party, and the

Ministers, to present the necessary evidence for the Board to make its determinations. As matters stand, based on Board Staff's refusal to provide particulars and the Ministers' broadly stated allegations, Alexion is substantially prejudiced in its ability to know the case it has to meet and to effectively respond. Alexion respectfully requests that the relief sought be granted.

THE FOLLOWING DOCUMENTARY EVIDENCE will be used at the hearing of the motion:

35. The Affidavit of Anna Di Domenico, sworn on 15 May 2015, and attachments.

Malcolm Ruby

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Date: May 15, 2015

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PATENTED MEDICINE PRICES REVIEW BOARD

**IN THE MATTER OF the *Patent Act*,
R.S.C., 1985, c. P-4, as amended**

**AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. ("Respondent")
and the medicine "Soliris"**

AFFIDAVIT OF ANNA DI DOMENICO

(REQUEST FOR PARTICULARS, CROSS-EXAMINATION OF ERIC LUN, and DIRECTIONS RE: MOTION TO STRIKE PASSAGES OF PROVINCIAL MINISTERS'AMENDED APPEARANCE)

1. I a law clerk who works with Alan West and Malcolm Ruby, partners who have carriage of this matter on behalf of the Respondent, Alexion Pharmaceuticals Inc. As such, I have knowledge of these proceedings and the facts deposed to in this affidavit.

2. On 20 January 2015, the Board issued its Notice of Hearing ("Notice") and Allegations relating to Alexion and the medicine Soliris. A copy is attached as **Exhibit "A"**.

3. On 12 February 2015, counsel for Alexion (Gowlings) wrote to Board Staff's counsel, (Perley-Robertson) confirming an agreement, subject to approval of the Hearing Panel, to modify the schedule for delivery of Alexion's Response, Board Staff's Reply, and the first case conference. The 12 February 2015 letter from Gowlings to Perley-Robertson also contained a request for particulars and disclosure of documents relating to Board Staff's calculations "concerning the impact of exchange rates on pricing of Soliris in the comparator countries listed in the Schedule to the *Patented Medicines Regulations*" and the "impact of exchange rates under the Price Comparison test." A copy is attached as **Exhibit "B"**.

4. In a letter dated 20 February 2015, Board Staff's counsel refused to provide particulars. A copy is attached as **Exhibit "C"**.

5. I am informed by Alan West, and believe, that to date no documents have been produced by Board Staff.

6. Alexion filed its Response on 9 March 2015. A copy is attached as **Exhibit "D"**.

7. On 9 March 2015, the Minister of Health for British Columbia ("BC Minister") filed an appearance on behalf of the BC Minister and the Minister of Health for Manitoba ("Ministers' Appearance"). A copy is attached as **Exhibit "E".**

8. On 17 March 17, 2015, counsel for the BC Minister of Health delivered correspondence detailing further issues they intended to rely upon in an Amended Appearance. A copy is attached as **Exhibit "F"**.

9. On 20 March 2015, Alexion delivered correspondence objecting to the proposed Amendment on the grounds that it was irrelevant to the HIPC test-related allegations referred to in the Allegations. A copy is attached as **Exhibit "G"**.

10. On 2 April 2015, counsel for the BC Minister of Health filed the Ministers' Amended Notice dated 13 March 2015, together with an affidavit of Eric Lun, sworn 1 April 2015. Copies are attached as **Exhibits "H" and "I"**.

11. On 10 April 2015, Board Staff filed a Reply ("Board Reply"). A copy is attached as **Exhibit "J"**.

12. In correspondence dated 16 April 2015, Alexion objected to alteration or expansion of the issues as stated in Board Staff's Reply. A copy is attached as **Exhibit "K"**.

13. In correspondence to the Board dated 23 April 2015, Board Staff repeated its assertion that the essential allegations were not about impact of foreign exchange rates, but that "based on the factors under section 85 of the Patent Act ... Alexion has been selling Soliris at a price that is excessive since 2012". A copy is attached as **Exhibit "L"**.

14. In correspondence dated 27 April 2015, Alexion asserted it was entitled to know the case to be met. A copy is attached as **Exhibit "M"**.

15. I am informed by Alan West, and believe, that on 29 April 2015 a Case Management Conference was held to schedule various matters. The Board issued an Order on 1 May 2015. A copy is attached as **Exhibit "N"**.

16. I am informed by Alan West, and believe, that without the particulars repeatedly requested from Board Staff as documented above, Alexion cannot properly plead to this case and will suffer significant prejudice as a consequence.

17. I swear this affidavit in support of the motion for particulars, cross-examination or Eric Lun, and directions concerning a motion to strike passages of the provincial Ministers' Amended Appearance, and for no other purpose.

SWORN BEFORE ME at the City of Toronto,
in the Province of Ontario
this 15th day of May 2015.

Original signature redacted

Commissioner for Taking Affidavits
ALAN WEST

Original signature redacted

ANNA DI DOMENICO

THIS IS **EXHIBIT "A"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.
ALAN WEST

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. (the "Respondent") and the medicine "Soliris"

NOTICE OF HEARING

TAKE NOTICE that the Patented Medicine Prices Review Board (the "Board") will hold a hearing in its offices in the Standard Life Centre, 333 Laurier Avenue West, 18th Floor, Ottawa, Ontario, on a date to be determined by the Hearing Panel no later than March 6, 2015.

A. Purpose of the Hearing

1. The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act* (the "Act"), the Respondent is selling or has sold the medicine known as Soliris in any market in Canada at a price that, in the Board's opinion, is or was excessive and if so, what order, if any, should be made.

B. Power of Board With Respect to Excessive Prices

2. In the event that the Board finds that the Respondent is selling Soliris in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the Respondent to cause the maximum price at which the Respondent sells Soliris in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.

3. In addition, in the event that the Board finds that the Respondent has, while a patentee, sold Soliris in any market in Canada at a price that, in the Board's opinion was excessive, the Board may, by order, direct the Respondent to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenue determined by it to have been derived by the Respondent from the sale of Soliris:

a) reduce the price at which the Respondent sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;

b) reduce the price at which the Respondent sells one other medicine to which a patented invention of the Respondent pertains in any market in Canada, to such extent and for such period as is specified in the order;

c) pay to Her Majesty in right of Canada an amount specified in the order.

4. Any other remedies Board Staff may seek and the Board may permit.

C. Grounds for the Proposed Orders and the Material Facts

5. Board Staff has conducted an investigation into the price of Soliris (Drug Identification Number (“DIN”) 2189015, a patented medicine currently sold in Canada by the Respondent. Soliris is sold in Canada in 10mg/mL. The material facts relied upon by Board Staff for the purpose of the Notice of Hearing and the order sought from the Board are described in the Statement of Allegations of Board Staff dated January 15, 2015, a copy of which is attached.

D. Procedure

6. The Board has a public interest mandate to conduct its hearings as expeditiously as fairness permits. The Board will conduct this proceeding in accordance with the Patented Medicine Prices Review Board Rules (the "Rules"), unless otherwise provided in this Notice of Hearing or in any subsequent communication from the Board.

7. The Board will conduct the hearing in public unless the Board is satisfied on representations made and evidence filed by the Respondent that specific, direct and substantial harm would be caused to the Respondent by the disclosure of information or documents at a public hearing, in which case the hearing or any part thereof may, at the discretion of the Board, be held in private.

E. Case Management Conference

8. A Case Management Conference will be held with Counsel and the Secretary of the Board on or before March 6, 2015, in accordance with section 22 of the Rules, for the purpose of

(a) fixing the hearing schedule;
(b) establishing the official language the parties wish to use during the proceeding;
(c) discussing the filing of evidence by the parties;
(d) considering the procedure to be followed and means of expediting the hearing, including determining whether written submissions will be submitted;
(e) determining the expected duration of the hearing;
(f) facilitating the exchange among the parties of information and documents to be submitted at the hearing; and
(g) identifying other issues to be resolved.

9. Witnesses are to be ready to testify throughout the days that will be set out for evidentiary matters, standing by where required in order to avoid delays or unutilized scheduled time.

10. Parties are required to file three (3) paper copies of documents. If a document is filed electronically, the three (3) paper copies must be filed with the Secretary of the Board within 48 hours of electronic filing. In addition, electronic documents must be filed as Portable Document Format (PDF) or in any format authorized by the Secretary, in accordance with section 14 of the Rules.

F. Notice of Appearance

11. Parties are to advise the Secretary of the Board, in writing (by e-mail or fax) and other parties of their legal representation.

G. Response

12. If the Respondent wishes to oppose the proposed order set out in the Statement of Allegations, the Respondent shall, no later than February 9, 2015, file with the Secretary of the Board and serve upon all other parties, in accordance with section 18 of the Rules, a response dated and signed by the Respondent. Take notice that if the Respondent has not filed a response by February 9, 2015, or within such longer period as the Board may by order provide, the Board may make any finding and issue any order pursuant to section 83 of the Act as it deems appropriate.

13. The Respondent should note that the Response constitutes a relatively general statement of the Respondent’s position.

H. Reply

14. If Board Staff wishes to reply to the Response, Board Staff shall, within 20 days after being served with the response, file with the Secretary of the Board and serve its reply upon the Respondent and all other parties.

I. Appearance by Minister

15. Ministers referred to in subsection 86(2) of the Act ("Ministers"), who intend to appear and make representations before the Board shall, in accordance with section 21 of the Rules, file with the Secretary of the Board and serve on all parties a notice of appearance, dated and signed by the said Ministers, on or before February 9, 2015.

J. Intervention

16. Any person, other than the Respondent and the Ministers, who claims an interest in the subject matter of this proceeding, may make a motion to the Board, in accordance with section 20 of the Rules, for leave to intervene in the proceeding.

K. Confidentiality Requests

17. Subsection 86(1) of the *Act* provides that "*A hearing under section 83 shall be held in public unless the Board is satisfied on representations made by the person to whom the hearing relates that specific, direct and substantial harm would be caused to the person by the disclosure of information or documents at a public hearing, in which case the hearing or any part thereof may, at the discretion of the Board, be held in private*."

18. Any claim for confidentiality, made in connection with a document filed with the Board or requested by the Board or any party, shall be filed with the Secretary of the Board and served on all parties and accompanied by the reasons thereof. Where it is asserted that specific, direct and substantial harm would be caused to the party claiming confidentiality, the party's claim shall contain sufficient details as to explain fully the nature and extent of such harm.

19. A party claiming confidentiality in connection with a document shall indicate whether the party objects to providing an abridged version of the document to other parties and, if so, shall state the party's reasons for the objection.

K. List of Supporting Documents

- ✓ Statement of Allegations of Board Staff dated January 15, 2015 and attachments
- ✓ *Patent Act* (sections 79 to 103)
- ✓ *Patented Medicines Regulations*
- ✓ Patented Medicine Prices Review Board Rules of Practice and Procedure
- ✓ Compendium of Policies, Guidelines and Procedures

DATED at Ottawa, this January 20, 2015

Original signed by

_____

Guillaume Couillard
Secretary of the Board

All information requests and/or correspondence should be addressed to:

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TO

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The Honourable Leo Glavine, M.L.A.
Minister of Health & Wellness
Minister responsible for Seniors
Province of Nova Scotia
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Halifax, Nova Scotia B3J 2R8

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Province of Prince Edward Island
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4th Floor Shaw Building,
Charlottetown, P.E.I.
C1A 7N8

The Honourable Steve Kent, M.L.A.
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and Minister Responsible for the Office of Public Engagement
Government of Newfoundland and Labrador
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St. John's, Newfoundland and Labrador
A1B 4J6

The Honourable Doug Graham, M.L.A.
Minister of Health and Social Services
Government of Yukon, H-1
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Whitehorse, Yukon
Y1A 2C6

The Honourable Glen Abernethy, M.L.A.
Minister of Health and Social Services
Minister Responsible for Seniors and Persons with Disabilities
Government of the Northwest Territories
Legislative Assembly
P.O. Box 1320
Yellowknife, NWT X1A 2L9

The Honourable Monica Ell, M.L.A.
Minister of Health
Government of Nunavut
P.O. Box 2410
Iqaluit, Nunavut
X0A 0H0

THIS IS **EXHIBIT "B"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.
ALAN WEST

12 February 2015

Malcolm N. Ruby
Direct 416-862-4314
Direct Fax 416-863-3614
malcolm.ruby@gowlings.com
File No. T999663

VIA E-MAIL: CMorris@perlaw.ca

Christopher P. Morris
Perley-Robertson, Hill & McDougall LLP
340 Albert Street
Suite 1400
Ottawa, Ontario
K1R 0A5

Dear Mr. Morris:

Re: IN THE MATTER OF the *Patent Act*, R.S.C. 1985, c. P-4, as amended AND IN THE MATTER OF Alexion Pharmaceuticals Inc. and the medicine "Soliris" Re: Schedule and Particulars of Allegations

We wish to re-confirm our understanding of the agreed-upon schedule and request further particulars and disclosure regarding the Statement of Allegations ("Statement").

Our understanding of the current schedule is:

1. Delivery of Alexion's Response to Statement of Allegations: 9 March 2015;

2. Delivery of Board Staff's Reply to the Response: 10 April 2015; and

3. Case Management Conference: No later than 30 April 2015.

The schedule is subject to any modifications that may be necessary as a result of interventions by provincial Attorneys General.

In our review of the Statement, we saw no details regarding Board Staff's analysis of the introductory price of Soliris, other than a bare mention that the Board recommended Soliris as a "breakthrough or substantial improvement" drug product when Alexion began selling Soliris in Canada at $224.7333/mL. Moreover, no mention is made in the Statement of the impact of foreign exchange rates on the outcome of the "Highest International Price Comparison test" Alexion's product is alleged to have failed.

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To fully appreciate and answer the claims in the Statement before delivering Alexion's Response, we would be grateful if you would provide the following particulars:

1. Any details concerning Board Staff's conclusions concerning the introductory price of Soliris; and

2. Board Staff's calculations concerning the impact of exchange rates on pricing of Soliris in the comparator countries listed in the Schedule to the *Patented Medicines Regulations*.

In addition, we request disclosure of any documents and/or records, such as notes, memoranda, or emails that illuminate or explain Board Staff's determinations concerning the introductory price and/or the impact of exchange rates under the Price Comparison test.

Please confirm the proposed schedule (subject to any modifications to accommodate provincial Attorneys General), and indicate when we can anticipate receiving a response to our other requests. We are hopeful that particulars and relevant documents can be delivered well in advance of the delivery date for Alexion's Response 9 March 2015.

Yours very sincerely,

GOWLING LAFLEUR HENDERSON LLP

Malcolm N. Ruby
MNR:gm:kam

TOR_LAW\ 8627475\2

THIS IS **EXHIBIT "C"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.
ALAN WEST

PERLEY-ROBERTSON, HILL & McDOUGALL LLP/s.r.l.

Lawyers / Patent & Trade-Mark Agents
Avocats / Agents de brevets et de marques de commerce

Reply to/Communiquez avec:
David Migicovsky
613.566.2833 dmigicovsky@perlaw.ca

February 20, 2015

BY EMAIL

Malcolm N. Ruby
Gowling Lafleur Henderson LLP
100 King Street West, Suite 1600
Toronto, ON M5X 1G5

Dear Mr. Ruby:

Re: IN THE MATTER OF Alexion Pharmaceuticals Inc. and the medicine "Soliris"
Our Reference: PMPR010

This is further to your letter to Mr. Morris of February 12, 2015. The schedule set out in your letter is correct. That said, the Panel's order regarding scheduling does not reflect the agreed upon schedule. Consequently, Board Staff may request additional time to complete its reply if necessary.

In response to the request for particulars, Board Staff asserts that:

1. Alexion was previously provided with information related to the introductory price of Soliris. We refer you to Board Staff's letter to Alexion dated June 21, 2011, which is attached for your reference.

2. Board Staff conducted its calculations concerning the impact of exchange rates in accordance with the *Patented Medicines Regulations* and the 2010 Compendium of Guidelines, Policies and Procedures as Alexion is aware and as alleged in paragraph 15 of the Statement of Allegations.

It follows therefore that the particulars are within Alexion's knowledge. In any event, Alexion does not require these particulars to enable it to plead.

Finally, Alexion's request for documents is premature. Board Staff will deliver its documents within a reasonable timeframe after the parties have exchanged pleadings.

Yours very truly,

Original signature redacted

David Migicovsky
20: dem

c.c. Alan West; Parul Shah, Christopher P. Morris

THIS IS **EXHIBIT "D"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.
ALAN WEST

PATENTED MEDICINE PRICES REVIEW BOARD

**IN THE MATTER OF the *Patent Act*,
R.S.C., 1985, c. P-4, as amended**

**AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. ("Respondent")
and the medicine "Soliris"**

RESPONSE TO THE STATEMENT OF ALLEGATIONS OF BOARD STAFF

Overview

1. Respondent Alexion Pharmaceuticals Inc. ("Alexion" or "Respondent") acknowledges the allegations in paragraphs 4, 6, 7, 8, 10, 11, 12, 13, 22, 23 and 24 of the Statement of Allegations of Board Staff ("Allegations").

2. Alexion denies the remainder of the allegations.

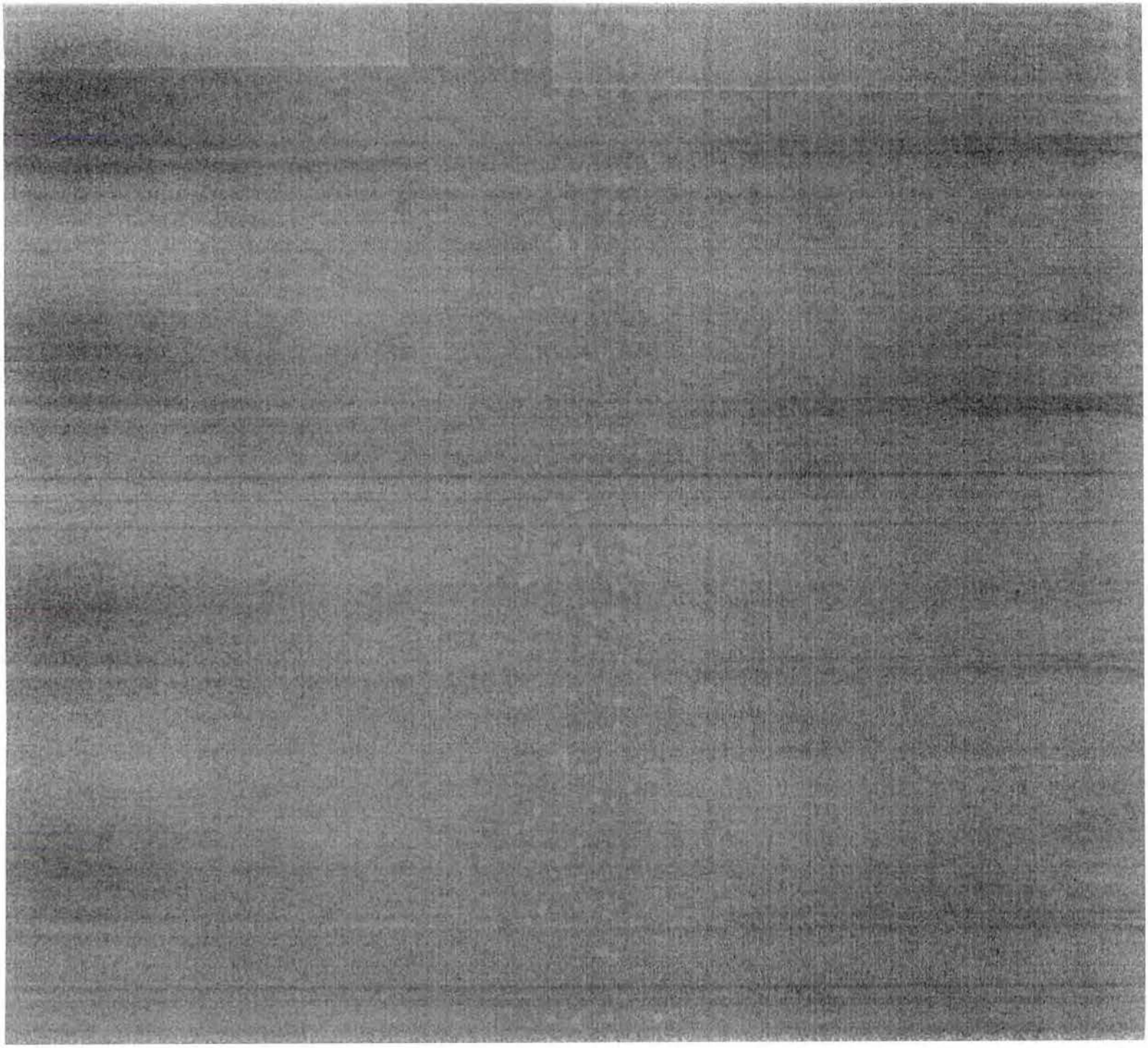
3. In its Allegations, Board Staff allege that the ex-factory price of Soliris has been "excessive" over a three-year period, beginning in 2012.

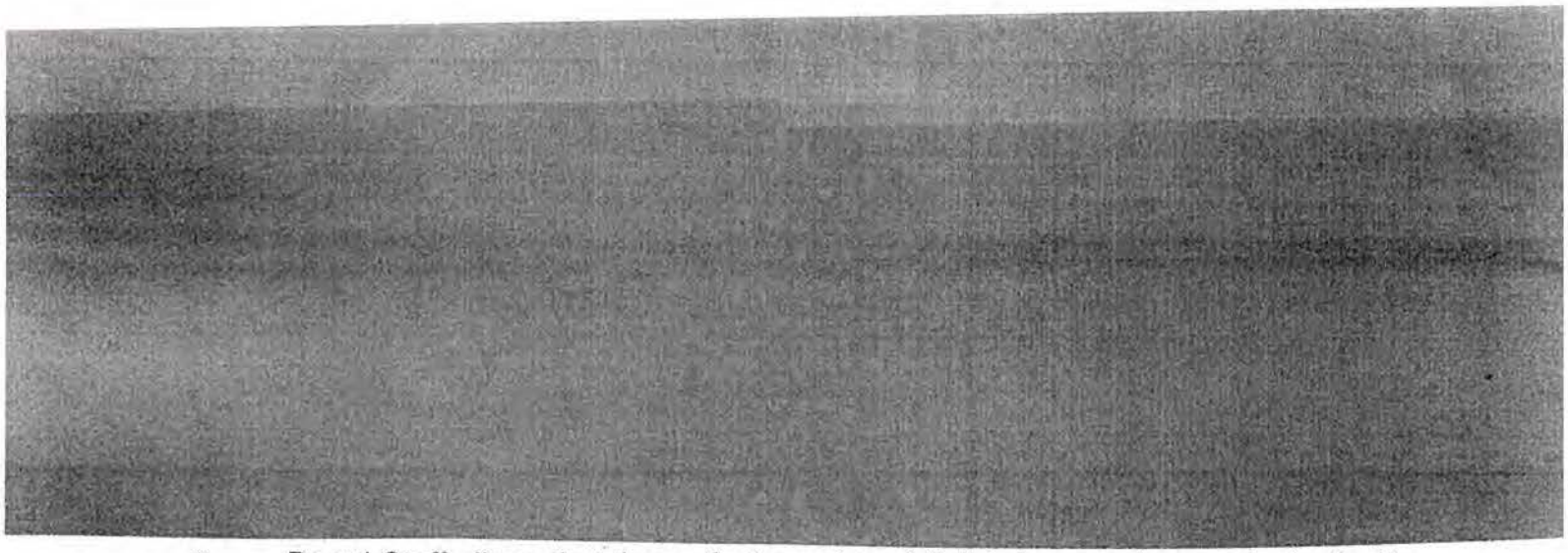
4. Board Staff have not alleged that the ex-factory price of Soliris was "excessive" when it was introduced in 2009 or before 2012.

5. The Canadian ex-factory price of Soliris has not increased since it was introduced.

6. Moreover, with minor exceptions, the ex-factory price of Soliris has not decreased in <u>any</u> of the seven reference countries where Soliris has been sold internationally since the product was first introduced to the Canadian market.

7. The following graphs illustrate the actual ex-factory prices of Soliris in Canada and the seven reference countries listed in the Regulations and the 2010 *Compendium of Guidelines, Policies and Procedures* (the "Guidelines")





8. Board Staff allege that the ex-factory price of Soliris became "excessive" after its introduction, *even though the ex-factory price has not increased in Canada and has not materially changed in any of the reference countries, except the United States where the price has increased.*

9. Despite the absence of price increases in Canada or decreases in any of the reference countries, Board Staff allege that prices in Canada became excessive in 2012 when the Canadian ex-factory price failed the "highest international price" test in the Guidelines due entirely to changes in exchange rates.

10. Board Staff have not explained in the Allegations how it was possible for an ex-factory price that was "non-excessive" in one year to become "excessive" in the next without a price increase in Canada or price decreases elsewhere. When asked for particulars to explain their allegation in this respect, Board Staff's counsel was unhelpful and provided no comprehensible response. Alexion reserves all its rights to amend once particulars are provided or ordered, but can only assume that it is only fluctuations in the international exchange rates that

made the Canadian ex-factory price *appear* to have increased relative to some reference countries when *applying the international price test in the Guidelines*.

11. Board Staff have apparently concluded (and refused to provide material details), that if the Canadian ex-factory price somehow 'fails' (in their determination) the "highest international price" Guidelines test , the price must be "excessive" under the criteria in subsection 85(1) of the *Patent Act* (the "*Act*"). The *Act* requires the Board to take into account all price factors in s. 85(1), and to reach a reasonable determination, based on all of these factors, whether a price is "excessive". Moreover, exchange rates are not a factor listed in s.85(1) of the *Act* and it is not evident how, without price increases in Canada and price decreases elsewhere, changes in exchange rates can result in a finding of excessive pricing under s.85(1).

12. In the Allegations, Board Staff acknowledge that the Guidelines are not binding on the Board. The Allegations, however, are clearly and solely predicated on Board Staff applying the Guidelines as if the Guidelines have prescriptive legal force.

13. The Allegations demonstrate the absurdity of applying the Guidelines in this case. Board Staff reach the arbitrary, impractical, and logically untenable position that a Canadian ex-factory price that did not change from the time the medicine was first sold in Canada and did not change in comparator countries (other than price increases in the US), went from being "non-excessive" to "excessive" based on the value of foreign currency fluctuations. The result is a virtual expropriation

of company revenues based on international currency fluctuations over which Alexion had no control and from which the *Act* does not purport to insulate Canadian purchasers. But even assuming the *Act* could reasonably be construed to cover international currency fluctuations, Board Staff cannot show in this case that any purchaser is actually worse off as a result of the fluctuations, which must be a necessary corollary of any determination of "excessive" pricing.

Board Staff's Errors

14. In its Allegations, Board Staff make at least five fundamental errors in reaching the conclusion that the price of Soliris has been "excessive" during the review period. They:

(a) fail to understand the meaning of "excessive" under the *Patent Act* and therefore misapply the actual test under subsection 85(1) of the *Act*, which requires the Board to take into consideration all factors under this subsection to rationally advance the purposes of the legislation;

(b) misapply the highest international price test in the Guidelines by treating it as binding, contrary to subsection 96(4) of the *Patent Act*;

(c) deviate from the economic rationale behind the Guidelines, which are intended to rationally advance the purposes of the *Act;*

(d) both in the Guidelines, and as applied in this case, Board Staff inconsistently use the word "price", sometimes to mean the nominal price (not adjusted for price level) and sometimes to mean the real price (adjusted for price level); and

(e) fail to explain and articulate how they applied international pricing from the reference countries, including the particular foreign prices and exchange

rates they used for comparative purposes, and all other factors, concepts, and assumptions they relied upon when comparing the sale, purchase, or price of Soliris in Canada and the reference countries.

Economic Analysis

15. Subsection 85(1) of the *Act* addresses the potential problem that a patentee's statutory monopoly during the exclusivity period might cause prices to rise to levels that will harm Canadian purchasers. The legislative intent of these provisions is not to regulate the prices of drugs *generally*. The purpose is to specifically address the potential for a patentee to abuse its patent monopoly for a patented medicine during the exclusivity period by causing prices for the medicine to be established at, or rise unacceptably to excessive levels. The provisions of the *Patent Act*, and accordingly the Board's determination whether the price of a drug is "excessive", must be interpreted in a manner consistent with that legislative purpose.

16. While the focus is obviously and necessarily on the price of the patentee's drugs in Canada, the *Act* nonetheless states that the Board must look to the "prices" of drugs in other countries: paragraph 85(1)(d). The purpose of looking at international prices is to provide an additional reference point when determining whether a "price" in Canada is or is not excessive. The word "price" is not defined in the *Act* itself.

17. Economists use the term "price" in different ways Often the word refers to a "nominal" price as expressed in historical monetary terms. By comparison a "real" price takes into account the effect of inflation. In nominal terms, the list price of

Soliris is unchanged since its introduction in 2009 whereas in real terms its price has declined by more than 8%.

18. As is well known, and uniformly recognized by economic agencies charged with making international price comparisons, conversion using nominal exchange rates does *not* capture changes or differences in real purchasing power. Exchange rates vary for many reasons other than changes in relative price levels across countries. For example, expectations regarding a central bank's monetary policy can affect an exchange rate. When *nominal* exchange rates are used to draw inferences about changes in *real* purchasing power, errors are inevitable—as the Board Staff's position in this case amply demonstrates.

19. The *Act* manifestly concerns the *real* cost to Canadian purchasers of patented medicines. At the domestic level, the *Act* permits prices of patented medicines to increase based on increases in Canada's Consumer Price Index (CPI). The CPI measures changes in Canada's domestic price level. If a medicine's nominal price increases at the same rate as the overall price level, then its "real" price remains unchanged. If the "nominal" price was not "excessive" initially, it cannot become "excessive" over time if its real price remains constant. If no CPI increases are sought, or applied, and the real price actually decreases, it tortures logic and language to assert, as Board Staff do, that a price that was not initially excessive, and that decreased over time, has become excessive.

20. It defies reason to read the *Patent Act* as meaning that an introductory price that was non-excessive, and that has declined in real terms since introduction, is

nevertheless excessive for reasons outside the Board's or the Patentee's control. Regardless of how the *Act* is read, it cannot have been intended to place revenue streams of Canada's suppliers of patented medicines, particularly those who do not increase their prices, at the mercy of the world's central bankers or other vagaries that cause international currency fluctuations.

21. The perversity of the Allegations are further illustrated by appreciating that patented drugs are what economists describe as "non-traded goods". These are products which cannot simply be purchased on the international market because of regulatory restrictions requiring the products to be purchased in Canada. Canadian purchasers cannot take advantage of changes in exchange rates to purchase products, like medicines, when the "nominal" prices of those drugs are lower in another jurisdiction.

22. When "nominal" prices decrease in another jurisdiction based on the relative strengthening of the Canadian dollar, there is no meaningful sense in which the price of a non-traded good in Canada has increased relative to the price of the same good in the foreign market. Buyers in the foreign market pay just as much, in real terms, as they did before the Canadian dollar strengthened —and so do Canadian purchasers. For traded goods, the deteriorating currency in a foreign market means that purchasers of traded goods in the foreign market are *worse* off and Canadians are *better* off. As a generalization, Canadians' money is now worth more than it was, but only for the purchase of traded goods.

23. The only sense in which Canadian prices have increased is that Canadian buyers pay more for a non-traded good than they would pay if that good were freely traded. In other words, because Canadian purchasers cannot buy medicines on the foreign market, they cannot take advantage of the (relatively) strong Canadian dollar. This constraint applies to <u>all</u> non-traded goods. Canadian buyers cannot, for example, "import" cheaper subway ticket prices from a foreign market. In the same sense, fees charged by doctors in Canada do not decrease when the Canadian dollar strengthens versus other currencies. It makes no sense to say, under these circumstances, that Canadian patients must "pay more" to see a doctor in Canada than they did before the dollar strengthened.

24. While the "price" of a drug in another country may be a useful factor in determining whether a price is "excessive" in Canada, Board Staff must compare prices in a way that makes economic sense and is consistent with the regulatory objectives of the *Act*. It is well known that comparing prices both internationally and over time is especially fraught with difficulty, and must be conducted with care to avoid perverse results like those Board Staff assert here. A purely mechanical and arbitrary application of the highest international price test in the Guidelines is contrary to legislative intent, defies economic sense, and leads to the absurd result that a price initially deemed "non-excessive" has become "excessive" because of currency fluctuations that make no difference whatsoever to buyers.

25. Indeed, given that Alexion has never taken any price increases to adjust for inflation, even CPI increases to which it is entitled under the Board's own

Guidelines, the price of Soliris in real terms has continually *decreased* since the drug was introduced in Canada.

26. Board Staff's position effectively expropriates revenues from Alexion based on foreign currency fluctuations over which Alexion has no control. If the Canadian dollar *strengthens vis-à-vis* the comparator countries Alexion must pay "excess revenues". If the Canadian dollar *weakens* against the same comparator currencies, however, Alexion cannot increase the price of Soliris to compensate for losses it may sustain beyond CPI rates. In effect, Board Staff wish to engage in a "heads I win, tails you lose" strategy under which it expropriates the benefit of a strengthening Canadian dollar and leaves Alexion to deal with the burden of a weak Canadian dollar by limiting increases to CPI rates. The *Act* was never intended to achieve such an arbitrary and perverse result. Indeed, the interpretation and application of the *Act* in the manner advanced by Board Staff, to enable the taking of property based on foreign exchange factors not found within the *Patent Act* and based on foreign transactions not within Alexion's control, contravenes the *Canadian Bill of Rights* in that it abrogates, abridges, infringes, and deprives Alexion of its right to a fair hearing and the enjoyment of property. Moreover, this interpretation does nothing to protect purchasers and may even deter manufacturers from selling in Canada.

27. Forcing drug manufacturers to disgorge revenues based on currency exchange rate fluctuations over which they have no control is directly contrary to the regulatory function of the Board, which is solely to determine whether the price of the drug, in Canada, is "excessive".

Other Material Facts

28. Board Staff have made several factual errors in the Allegations to colour the analysis and to provoke an incorrect result. For example, in paragraph 1, Board Staff allege that the price of Soliris is "over half a million dollars per patient". This is untrue. Soliris is dosed according to a patient's weight. Depending on the patient's weight, the cost can be as low as $80,000 per year. The same error is repeated in paragraph 9.

29. Board Staff state—repeatedly—that the price of Soliris in Canada is "higher [than] in the United States": see paras. 2, 19, 20 and 26. Even if true, this is irrelevant. Under its own Guidelines, the US price is not determinative of anything. The price of Soliris depends on comparisons with 7 reference countries of which the US is but one.

30. Board Staff have alleged, in paragraphs 19 through 21, that Alexion's price is higher than Guidelines for 2014 and that "Alexion continues to sell Soliris to Canadians at the highest international price". This is also untrue and has not been established by Board Staff.

Original signature redacted

Malcolm Ruby
GOWLING LAFLEUR HENDERSON LLP
1 First Canadian Place
100 King Street West, Suite 1600
Toronto ON M5X 1G5

Date: March 9, 2015

GOWLING LAFLEUR HENDERSON LLP
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Lawyers for the Respondent

TO: **PATENTED MEDICINE PRICES REVIEW BOARD**
Legal Services Branch
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1
Tel: (613) 952-7623
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Guillaume Couillard *(Secretary of the Board)*
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Parul Shah *(Legal Counsel PMPRB)*
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David Migicovsky
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Lawyers for Board Staff

AND TO: **MEDICAL BENEFICIARY AND PHARMACEUTICAL SERVICES**
British Columbia Ministry of Health
PO Box 9652 STN PROV GOVT
Victoria BC V8W 9P4
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Barbara Walman *(Assistant Deputy Minister)*
Barbara.Walman@gov.bc.ca

Representative for the Interveners, the Provinces and Territories - British Columbia, Yukon, Saskatchewan, Manitoba, Ontario, New Brunswick, Newfoundland, and Nova Scotia

TOR_LAW\ 8649381\1

THIS IS **EXHIBIT "E"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.
ALAN WEST

PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c.P-4, as amended

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. (the "Respondent") and the medicine "Soliris"

NOTICE OF APPEARANCE

TAKE NOTICE THAT the Ministers of Health for the Provinces of British Columbia and Manitoba (collectively, "the Ministers of Health") intend to appear and make representations with respect to this matter on the following basis:

1. The Minister of Health for the Province of British Columbia, on behalf of the Ministers of Health, intends to make representations supporting the proposed Orders of the Board on the basis set out by Board Staff in the Statement of Allegations of Board Staff ("the Statement of Allegations").

2. The Minister of Health of Manitoba has consented to the Minister of Health for British Columbia making representations on behalf of the Ministers of Health. Attached to this Notice of Appearance as Schedule A is a copy of the consent letters.

3. The Ministers of Health intend to rely upon the material facts set out in the Statement of Allegations, and upon the documents noted in the List of Attachments to the Statement of Allegations.

4. The Ministers of Health also intend to rely upon the Affidavit of Eric Lun which will be filed at a later date.

5. The Ministers of Health may also rely upon any documents submitted by a participant to the hearing, and any affidavits filed in the proceeding.

6. Service of any documents in this proceeding may be effected upon the Ministers of Health by serving:

    Barbara Walman
    Assistant Deputy Minister
    Medical Beneficiary and Pharmaceutical Services
    British Columbia Ministry of Health
    PO Box 9652, STN PROV GOVT
    Victoria, British Columbia V8W 9P4
    Barbara.Walman@gov.bc.ca

    with the Minister of Health of British Columbia consenting to accept service of any documents in this proceeding on behalf of the Ministers of Health, and the Minister of Health of British Columbia agreeing to distribute any documents served upon the Minister of Health of British Columbia to the Ministers of Health, as required.

7. The Ministers of Health request that participation in the hearing (and other related meetings) be permissible by teleconference.

DATED at Victoria, British Columbia, this _9th_ day of March, 2015.

ON BEHALF OF THE MINISTER OF HEALTH FOR THE PROVINCE OF BRITISH COLUMBIA

Original signed by

_____

TO: The Secretary of the Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

AND TO: Mr. John Haslam
President and General Manager
Alexion Pharmaceuticals Inc.
400 Applewood Crescent
Suite 120
Vaughan, Ontario L4K 0C3

THIS IS **EXHIBIT "F"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signed by

A Commissioner etc.
ALAN WEST

BRITISH COLUMBIA

March 17, 2015

Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

BY EMAIL AND COURIER

Attention: Guillaume Couillard
Secretary of the Board

Dear Sir:

RE: IN THE MATTER OF the *Patent Act*, R.S.C. 1985, c. P-4, as amended AND IN THE MATTER OF Alexion Pharmaceuticals Inc. ("the Respondent") and the medicine "Soliris"

I am the solicitor for Her Majesty the Queen in Right of the Province of British Columbia, as represented by the Minister of Health ("the Minister"). I enclose a Notice of Appearance pursuant to Rule 13 of the Rules of Practice and Procedure.

I am writing in response to your letter to Barbara Walman dated March 13, 2015.

Please accept this letter as a request by the Minister to the Panel for an order:

1. extending the time for the Minister to file an Amended Notice of Appearance, with the Amended Notice of Appearance to be filed by March 27, 2015;
2. permitting the Minister to make representations in the hearing to the Panel on behalf of the Ministers of Health of Ontario, Manitoba, and Newfoundland and Labrador.

1. <u>Extension of time to file an Amended Notice of Appearance:</u>

The Notice of Appearance filed by the Minister on March 9, 2015 indicated that the Minister would be relying on the Statement of Allegations of Board Staff, and on the List of Documents set out in the Statement of Allegations of Board Staff. If granted the extension of time to file an Amended Notice of Appearance, the Minister will file an Amended Notice of Appearance providing details of further material facts that the Minister intends to rely upon, primarily related to:

(a) recommendations made by the Common Drug Review in relation to reimbursement of Soliris by public drug plans;

Ministry of Justice
Legal Services Branch
Health and Social Services
Mailing Address:
PO BOX 9280 STN PROV GOVT
Victoria BC V8W 9J7
Location:
1001 Douglas Street
Victoria BC
Telephone: 250 356-8931
Facsimile: 250 356-8992

(b) the process by which public drug plans review medicines such as Soliris for potential reimbursement;
(c) the cost of Soliris in comparison to other publicly-funded medicines; and
(d) the importance of the public list price of a medicine in relation to negotiations and other reimbursement policies.

These facts will be set out in detail in the Affidavit of Eric Lun, as referred to in the Notice of Appearance filed on March 9, 2015. The Affidavit of Eric Lun will be filed by the Minister at any time the Panel might order, whether with the Amended Notice of Appearance or at a later date in the proceedings.

The Minister respectfully submits that if the Panel grants the extension of time for the Minister to file an Amended Notice of Appearance, it will cause no prejudice to any party. The Order Regarding Scheduling dated February 13, 2015 permitted the Respondent until March 9, 2015 to file a response; that same Order permitted the Minister until March 9, 2015 to file a Notice of Appearance. Therefore, the Respondent had no opportunity to refer in its response to any statement of representations that may have been made in the Notice of Appearance filed by the Minister; any amendments to the Notice of Appearance will thus not necessitate any amendments to the response filed by the Respondent.

The Minister further respectfully submits that permitting an extension of time to file an Amended Notice of Appearance will assist the Panel and the parties in the hearing. The Minister, as a public payor for Soliris, will be able to provide information to the Panel that is not otherwise available through Board Staff and the Respondent, and the Panel will therefore be able to make its decision on the basis of a broader scope of evidence than if the Minister was not permitted an extension of time to file an Amended Notice of Appearance.

2. Permission for the Minister to make representations on behalf of the Ministers of Health of Ontario, Manitoba, and Newfoundland and Labrador:

As indicated in the Notice of Appearance filed by the Minister on March 9, 2015 and subsequent correspondence with the Board, the Ministers of Health of Ontario, Manitoba, and Newfoundland and Labrador (collectively, "the Represented Ministers of Health") have consented to the Minister making representations to the Panel in the hearing on their behalf. Consent forms signed by the Represented Ministers of Health are enclosed with this letter.

The Represented Ministers of Health share similar concerns as the Minister in relation to the pricing of Soliris, and the Represented Ministers of Health and the Minister are all of the view that it is important for the Panel to be aware that more than one jurisdiction has concerns about the price of Soliris. On the other hand, the information that could be provided to the Panel by the Represented Ministers of Health is very similar to the information that could be provided by the Minister (as noted in paragraphs (a) to (d) above); for the purposes of the hearing, it would be more efficient and practical if only one jurisdiction presented the relevant information. The Minister has agreed to present the information on behalf of British Columbia and on behalf of the Represented Ministers of Health.

All of which is respectfully submitted,

Original signed by

Sharna Kraitberg
Solicitor for Her Majesty the Queen in Right of the Province of British Columbia,
as represented by the Minister of Health

Encls.

cc: Barbara Walman, ADM, Medical Beneficiary and Pharmaceutical Services Division, BC Ministry of Health

David Migicovsky, Solicitor for Board Staff

Malcolm N. Ruby and Alan West, Solicitors for Alexion Pharmaceuticals Inc.

THIS IS **EXHIBIT "G"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.

ALAN WEST

March 20, 2015

Alan West
Direct 416-862-4308
Direct Fax 416-863-3480
alan.west@gowlings.com
File No. T999663

BY EMAIL: guillaume.couillard@pmprb-cepmb.gc.ca
and OVERNIGHT COURIER (to Mr. Mr. Guillaume Couillard only)

Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1

Attention: Mr. Guillaume Couillard, Secretary of the Board

BY EMAIL ONLY:

PATENTED MEDICINE PRICES REVIEW BOARD
Legal Services Branch
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1

Attention : Ms. Parul Shah , Legal Counsel PMPRB

PERLEY-ROBERTSON HILL & MCDOUGAL LLP
340 Albert Street
Suite 1400
Ottawa, ON K1R 7Y6

Attention: Messrs. David Migicovsky and Christopher Morris
Lawyers for Board Staff

gowlings

Ministry of Justice
Legal Services Branch
PO Box 9280 STN PROV GOVT
1001 Douglas Street
Victoria, BC V8W 9J7

Attention: Ms. Sharna Kraitberg
Lawyer for Her Majesty the Queen in Right of the Province of British Columbia, as represented by the Minister of Health
Representative for the Interveners, the Provinces of Manitoba, Ontario, and Newfoundland and Labrador

Dear Mr. Couillard and Counsel:

Re: Hearing into the matter of Alexion Pharmaceuticals Inc. and the medicine "Soliris"

Attached is Alexion's Objection to the Ministers' (of British Columbia, Manitoba, Newfoundland and Labrador, and Ontario) request to file an Amended Notice of Appearance.

Yours very truly,

GOWLING LAFLEUR HENDERSON LLP

Original signature redacted

Alan West

ANW:gm
Enclosure

TOR_LAW\ 8655646\1

PATENTED MEDICINE PRICES REVIEW BOARD

**IN THE MATTER OF the *Patent Act*,
R.S.C., 1985, c. P-4, as amended**

**AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. ("Respondent")
and the medicine "Soliris"**

ALEXION OBJECTION TO AMENDMENT OF MINISTERS' APPEARANCE

1. On 20 January 2015, the Board issued its Notice of Hearing ("Notice") and Statement of Allegations ("Allegations") relating to Alexion Pharmaceuticals Inc. ("Alexion" or "Respondent") and the medicine Soliris. The Board's Notice stated that the "material facts relied upon by Board Staff" were described within the Allegations.

2. The Board's initial correspondence indicated that the public hearing date would be fixed by the Hearing Panel at a case conference to be convened no later than 6 March 2015.

3. On 22 January 2015, the Board issued a press release repeating the allegation of "excessive pricing" against Alexion.

4. The principal assertion in the Allegations is that Alexion has sold Soliris to Canadians "at the highest international price among the comparator countries" listed in the Board's 2010 Compendium of Guidelines, Policies, and Procedures ("Guidelines"). The remedy requested is that Alexion be ordered to "stop selling Soliris at an excessive price" and to disgorge revenues Alexion "has generated from the sale of Soliris at an excessive price."

5. Paragraphs 14 – 21 of the Allegations describe an investigation conducted by Board Staff based upon the Highest International Price Comparison ("HIPC") test found in the Guidelines. The sole theory upon which the allegation of excessive pricing is based relates to alleged application of the HIPC. There is no allegation that any test other than the HIPC, which presumably applies the statutory factor found in subsection 85(1)(c)

("the prices at which the medicine...[has] been sold in countries other than Canada"), is implicated or violated.

6. Alexion was initially given until 9 February 2015 to file a Response to the Allegations. Board Staff were initially given 20 days from delivery of the Response to file a Reply.

7. Copies of the Board's documents, including the Notice and Allegations, were also provided to the Ministers of Health of the various Provinces and Territories ("Ministers"). The Ministers were also directed to deliver a Notice of Appearance by 9 February 2015.

8. On 12 February 2015, counsel for Alexion (Gowlings) wrote to Board Staff's counsel, (Perley-Robertson) confirming an agreement, subject to approval of the Hearing Panel, to modify the schedule for delivery of Alexion's Response, Board Staff's Reply, and to re-scheduling the first case conference.

9. The 12 February 2015 letter from Gowlings to Perley-Robertson also contained a request for particulars and disclosure of documents relating to Board Staff's calculations "concerning the impact of exchange rates on pricing of Soliris in the comparator countries listed in the Schedule to the *Patented Medicines Regulations*" and the "impact of exchange rates under the Price Comparison test."

10. On 13 February 2015, the Hearing Panel issued an order adjusting the schedule ("First Scheduling Order"). Alexion was given until 9 March 2015 to file a Response, the Ministers were given until 9 March 2015 to file Notices of Appearance, and Board Staff were given 20 days from receipt of Alexion's Response to file a Reply.

11. On 20 February 2015, counsel for Board Staff delivered a response to the request for particulars and disclosure of documents. Board Staff's counsel unhelpfully refused to provide particulars about exchange rate calculations. Board Staff did indicate that documents would be delivered "within a reasonable time frame after the parties' exchange pleadings" although, to date (almost 2 weeks after the Response was delivered), no documents have been produced by Board Staff.

12. Alexion filed its Response on 9 March 2015 consistent with the Hearing Panel's First Scheduling Order. The Response notes that the Introductory Maximum Non-Excessive ("MNE") for Soliris approved by Board Staff, $223.21, has not increased since Soliris was introduced to the Canadian market in 2009. The Response further notes that

Alexion has foregone any increases in price based on the Consumer Price Index ("CPI"), meaning that the price of Soliris has actually decreased in relative terms since the medicine was first introduced to the Canadian market in 2009. Indeed, as the Response notes, the allegation of "excessive" pricing under the HIPC is not based on actual price increases for Soliris in Canada or price decreases for Soliris in the comparator countries listed in the Guidelines: rather, the allegation is based solely upon fluctuations in the value of international currencies compared to the Canadian dollar. In sum, Alexion asserts in the Response that Board Staff are effectively comparing the relative value of currencies of various jurisdictions rather than the actual prices of Soliris in Canada and the comparator countries.

13. As defined in the Allegations and Response, the sole issue for the Hearing Panel is whether Alexion can be made accountable for fluctuations in the value of international currencies over which Alexion has no control.

14. On 9 March 2015, the Minister of Health for British Columbia ("BC Minister") filed a Notice of Appearance on behalf of the BC Minister and the Minister of Health for Manitoba ("Ministers' Appearance"). The Ministers' Appearance stated that the Ministers intended "to rely upon the material facts set out in", and the documents appended to, the Allegations . The Ministers' Appearance also made reference to an "Affidavit of Eric Lun which will be filed at a later date" and "any documents submitted by a participant to the hearing." There was no suggestion in the Ministers' Appearance that the Ministers would be referring to evidence or issues differing from the international pricing issue contained in the Allegations.

15. On 17 March 2015, eight days after the Ministers' Appearance was filed according to the Board's 9 March deadline, the BC Minister purported to file a separate Notice of Appearance and request the right to amend the Ministers' Appearance. In the accompanying cover letter, counsel for the BC Minister asked the Hearing Panel to extend the time for filing an Amended Notice of Appearance and to permit the BC Minister to make representations in the hearing on behalf of the Ministers of Health of Ontario, Manitoba, and Newfoundland and Labrador.

16. If granted an extension to file an Amended Appearance, counsel for the BC Minister has indicated that the BC Minister will provide "details of further material facts that the Minister intends to rely upon primarily" that relate to:

    (a) recommendations made by the Common Drug Review in relation to reimbursement of Soliris by public drug plans;

    (b) the process which public drug plans review medicines such as Soliris for potential reimbursement;

    (c) the cost of Soliris in comparison to other publicly-funded medicines; and

    (d) the importance of the public list price of a medicine in relation to negotiations and other reimbursement policies."

17. These "concerns" relating to "the pricing of Soliris" raised by the BC Minister bear no relation to the investigation conducted by Board Staff or the sole issue to be determined by the Hearing Panel, which relate entirely to whether Alexion's Canadian pricing violates the HIPC test.

18. The proposed material facts articulated in the BC Minister's letter have nothing whatsoever to do with comparisons of the price of Soliris in Canada with prices in countries where the medication is sold outside Canada. Indeed, for purposes of this proceeding, the Common Drug Review, review procedures of public drug plans, cost of Soliris compared with other publicly-funded medicines in Canada, and public list prices and reimbursement policies, have no relevance to any of the applicable factors under section 85 (1) referred to in the Allegations.

19. It will cause Alexion considerable inconvenience, expense, and prejudice to meet what are essentially issues irrelevant to those contained in the Allegations. Granting the amendment will also create significant delay in the conduct of the hearing.

20. The hearing, it is respectfully submitted, deals with the narrow issue of how the Board should treat fluctuations in international exchange rates when considering the HIPC test. The BC Minister's request is a thinly veiled attempt to convert the hearing into a broad inquiry into the procurement of patented medicines by public entities across Canada.

21. Alexion therefore respectfully submits that the request by the BC Minister should be dismissed. The Board should order that the BC Minister, and any other provincial or territorial minister, should be restricted to addressing the issues and material facts in the pleadings relating to application of the HIPC test in this case.

Original signature redacted

Malcolm Ruby

GOWLING LAFLEUR HENDERSON LLP
1 First Canadian Place
100 King Street West, Suite 1600
Toronto ON M5X 1G5

Date: March 20, 2015

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Lawyers for the Respondent

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Ms. Sharna Kraitberg
Sharna.Kraitberg@gov.bc.ca
Lawyer for Her Majesty the Queen in Right of the Province of British Columbia, as represented by the Minister of Health
Representative for the Interveners, the Provinces of Manitoba, Ontario, and Newfoundland and Labrador

THIS IS **EXHIBIT "H"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.
ALAN WEST

PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c.P-4, as amended

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. (the "Respondent") and the medicine "Soliris"

AMENDED NOTICE OF APPEARANCE

TAKE NOTICE THAT Her Majesty the Queen in Right of the Province of British Columbia, as represented by the Minister of Health ("the Minister of Health for British Columbia") ~~the Ministers of Health for the Provinces of British Columbia and Manitoba (collectively, "the Ministers of Health")~~ intends to appear and make representations with respect to this matter on the following basis:

1. The Minister of Health for ~~the Province~~ of British Columbia, on its own behalf and on behalf of the Ministers of Health for the Provinces of Ontario, Manitoba and Newfoundland and Labrador (collectively, "the Ministers of Health"), intends to make representations supporting the proposed Orders of the Board on the basis set out by Board Staff in the Statement of Allegations of Board Staff ("the Statement of Allegations"), but requesting that the Board order, pursuant to section 83 of the *Patent Act*, that:
   (a) the Respondent reduce the price of Soliris to a price that does not exceed the lowest price for Soliris among all comparator countries; and
   (b) the Respondent offset cumulative excess revenues that it has received by paying to the federal government an amount equal to the excess revenues the Board estimates that the Respondent has generated from the sale of Soliris at an excessive price, with the Board to use the lowest price for Soliris among all comparator countries as the basis for the calculation.

2. The Ministers of Health of Ontario, Manitoba and Newfoundland and Labrador have consented to the Minister of Health for British Columbia making representations on behalf of the Ministers of Health. Attached to this Notice of Appearance ~~as Schedule A is a copy~~ are copies of the consent letters.

3. The Ministers of Health intend to rely upon the material facts set out in the Statement of Allegations, and upon the documents noted in the List of Attachments to the Statement of Allegations.

4. The Ministers of Health also intend to rely upon the Affidavit of Eric Lun, ~~which will be filed at a later date~~ sworn April 1, 2015 and filed herein, and specifically upon the following facts as stated in the Affidavit of Eric Lun:

   (a) the process by which provincial governments review medicines such as Soliris for potential reimbursement;

   (b) the cost of Soliris in comparison to other publicly-funded medicines;

   (c) the importance of the public list price of a medicine in relation to negotiations between provincial governments and suppliers and in relation to other reimbursement policies;

   (d) the recommendations made by the Common Drug Review in relation to the reimbursement of Soliris by provincial governments.

5. The Ministers of Health also intend to rely upon the following documents attached as exhibits to the Affidavit of Eric Lun:

   (a) Canadian Expert Drug Advisory Committee Recommendation on Soliris for Indication of Paroxysmal Nocturnal Hemoglobinuria;

(b) Canadian Drug Expert Committee Recommendation on Soliris for Indication of Atypical Hemolytic Uremic Syndrome;

(c) Common Drug Review Submission Status summary.

6. The Ministers of Health may also rely upon any documents submitted by a participant to the hearing, and any affidavits filed in the proceeding.

7. Service of any documents in this proceeding may be effected upon the Ministers of Health by serving:

Ministry of Justice, Legal Services Branch
PO Box 9280 Stn Prov Govt
1001 Douglas Street
Victoria, BC V8W 9J7

Attention: Sharna Kraitberg
Phone: 250-356-8931
Fax: 250-356-8992
E-mail: sharna.kraitberg@gov.bc.ca

with the Minister of Health for ~~of~~ British Columbia consenting to accept service of any documents in this proceeding on behalf of the Ministers of Health, and the Minister of Health for ~~of~~ British Columbia agreeing to distribute any documents served upon the Minister of Health for ~~of~~ British Columbia to the Ministers of Health of Ontario, Manitoba and Newfoundland and Labrador, as required.

8. The Ministers of Health request that participation in the hearing (and other related meetings) be permissible by teleconference.

DATED at Victoria, British Columbia, this 2nd day of April, 2015.

Original signature redacted

Sharna Kraitberg, Counsel for the Minister of Health for British Columbia

TO: The Secretary of the Patented Medicine Prices Review Board

Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

AND TO: Christopher Morris and David Migicovsky
Counsel for Board Staff

Perley-Robertson Hill & McDouglas LLP
340 Albert Street
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Ottawa, ON K1R 7Y6

AND TO: Parul Shah
Legal Counsel PMPRB

Patented Medicine Prices Review Board
Legal Services Branch
Standard Life Centre
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Ottawa, Ontario K1P 1C1

AND TO: Malcolm N. Ruby and Alan West
Counsel for the Respondent

Gowling LaFleur Henderson LLP
1 First Canadian Place
100 King Street West, Suite 1600
Toronto, ON M5X 1G5

PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c.P-4, as amended

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. (the "Respondent") and the medicine "Soliris"

CONSENT FOR REPRESENTATION

I, [redacted], have reviewed the draft Notice of Appearance to be submitted by the Minister of Health of British Columbia in the Patented Medicine Prices Review Board Hearing (the "Hearing") related to the pricing of the drug product "Soliris".

I hereby consent to the Minister of Health for British Columbia making representations to the Hearing on behalf of the Minister of Health for the Province of Ontario.

DATED at Toronto, this 13th day of March, 2015.

MINISTER OF HEALTH FOR THE PROVINCE OF ONTARIO

Original signature redacted

TO: The Secretary of the Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c.P-4, as amended

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. (the "Respondent") and the medicine "Soliris"

CONSENT FOR REPRESENTATION

I, Shawn Bloody, have reviewed the draft Notice of Appearance to be submitted by the Minister of Health of British Columbia in the Patented Medicine Prices Review Board Hearing (the "Hearing") related to the pricing of the drug product "Soliris".

I hereby consent to the Minister of Health for British Columbia making representations to the Hearing on behalf of the Minister of Health for the Province of Manitoba.

DATED at 1:56 pm, this 5th day of March, 2015.

MINISTER OF HEALTH FOR THE PROVINCE OF MANITOBA

Original signature redacted

TO: The Secretary of the Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c.P-4, as amended

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. (the "Respondent") and the medicine "Soliris"

CONSENT FOR REPRESENTATION

I, Bruce Cooper, have reviewed the draft Notice of Appearance to be submitted by the Minister of Health of British Columbia in the Patented Medicine Prices Review Board Hearing (the "Hearing") related to the pricing of the drug product "Soliris".

I hereby consent to the Minister of Health for British Columbia making representations to the Hearing on behalf of the Minister of Health and Community Services for the Province of Newfoundland and Labrador.

DATED at St. John's in the province of Newfoundland and Labrador this 9th day of March, 2015.

MINISTER OF HEALTH AND COMMUNITY SERVICES FOR THE PROVINCE OF NEWFOUNDLAND AND LABRADOR

Original signature redacted

Minister or authorized designate

TO: The Secretary of the Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

THIS IS **EXHIBIT "I"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.

ALAN WEST

PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c.P-4, as amended

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. (the "Respondent") and the medicine "Soliris"

AFFIDAVIT OF ERIC LUN

I, Eric Lun, of New Westminster, British Columbia, SWEAR THAT:

1. I am the Executive Director of the Drug Intelligence and Optimization Branch, Medical Beneficiary and Pharmaceutical Services Division of the Ministry of Health of British Columbia ("the Ministry of Health"). As such, I have personal knowledge of the facts and matters hereinafter deposed to in this Affidavit, except where stated to be based on information and belief, and where so stated I verily believe the same to be true.

2. I am making this Affidavit on behalf of the Ministry of Health, but I am advised by my counter-parts in Ontario, Manitoba, and Newfoundland and Labrador ("the Represented Jurisdictions") that they support the position set out in this Affidavit.

3. The reason that the Ministry of Health and the Represented Jurisdictions seek to participate in this matter is to provide the Board with information about public funding of medicines in general and eculizumab (Soliris) in particular, and to request that the Board order that the Respondent reduce the price of Soliris to match the lowest price for Soliris among all comparator countries, both prospectively and retroactively.

4. The Ministry of Health operates the PharmaCare Program, which provides financial assistance to eligible British Columbia residents for the purchase of certain eligible prescription drugs and designated medical supplies.

5. The Ministry of Health also provides financial assistance on an exceptional basis for the purchase of the drug product Soliris to certain individuals in British Columbia who have been diagnosed with Paroxysmal Nocturnal Hemoglobinuria ("PNH").

6. I am advised by my counter-parts in the Represented Jurisdictions that the provincial governments of those jurisdictions also provide financial assistance for the purchase of Soliris, either through their public drug plans or through other public funding mechanisms.

7. At the Canadian list price of $6,742.50 per 300 mg vial and using recommended doses, the annual cost of Soliris for treatment of PNH is approximately $540,000 in the first year of treatment and $526,000 in subsequent years per patient. At list price, the cost of Soliris for treatment of Atypical Hemolytic Uremic Syndrome ("aHUS") is more than $700,000 per year per patient, based on recommended doses. As these medications may be used on a long-term basis (or potentially for the rest of a patient's life), the cumulative drug costs at list prices for 5, 10 or 20 years of therapy for a single PNH patient may be more than $2.5 million, $5 million, or $10 million, respectively.

8. The cost of Soliris is significantly higher than most other drugs funded by provincial governments for other diseases. This results in an opportunity cost, such that the funding of one patient on Soliris will result in fewer dollars for numerous patients with other diseases. By way of illustration, in British Columbia, the average annual PharmaCare drug ingredient expenditure per beneficiary is approximately $950 (based on PharmaCare data in FY 12/13 during which 722 other unique drugs were covered; http://www.health.gov.bc.ca/pharmacare/pdf/PCareTrends2012-13.pdf). On an opportunity cost basis, for example, this means that the expenditure used to fund Soliris for a single PNH patient could have been used to provide drug coverage for more than 550 other PharmaCare beneficiaries, on average.

9. Even when compared to other high cost drugs funded by provincial governments for other diseases, the cost of Soliris is significantly more expensive. To illustrate this, I provide the following examples of certain other drugs considered high cost and

funded by the Ministry of Health (the stated drugs costs are based upon list cost and do not include other mark ups):

(a) Infliximab (Remicade) costs up to $25,000 per year per patient. Infliximab is used for the long-term symptomatic treatment of various rheumatic or gastrointestinal disorders.

(b) Sofosbuvir-ledipasvir (Harvoni) costs about $70,000 per patient for a 12-week treatment course and is used as a potentially curative treatment for chronic hepatitis C infection.

(c) Ivacaftor (Kalydeco) costs about $306,000 per year per patient and is used for the long-term symptomatic treatment of a rare form of cystic fibrosis, and like Soliris is funded on an exceptional case basis in BC.

(d) Imiglucerase (Cerezyme) costs about $350,000 per year per patient and is used for the long-term symptomatic treatment of the rare Gaucher's disease, and like Soliris is funded on an exceptional case basis in BC.

10. The provincial governments in Canada are major payors for Soliris for the treatment of PNH, and therefore the provincial governments have a critically vested interest in the price of this drug product.

11. The Common Drug Review (CDR) reviews drugs for potential reimbursement by participating jurisdictions. In 2010, the CDR's advisory committee, the Canadian Expert Drug Advisory Committee ("CEDAC"), recommended that Soliris not be listed at the submitted price for treatment of PNH, stating that, "Eculizumab would not be considered cost-effective without a substantial reduction in the submitted price." Attached to this my Affidavit and marked as Exhibit A is a copy of the CEDAC's Recommendation on Soliris for PNH.

12. In agreeing to consider funding Soliris through government funding, the provinces and territories completed national negotiations for a confidential price for the product for its use in PNH. To secure confidential lower prices, participating jurisdictions each complete their own confidential product listing agreements with the

manufacturer and therefore cannot disclose the terms or conditions of such agreements. However, the list price of Soliris is referenced in the negotiations in order to determine overall value. Therefore, an excessive list price results in provincial governments being inherently disadvantaged in the listing negotiations and in the subsequent ongoing funding of Soliris purchases.

13. Because public government payors in Canada have negotiated a price lower than the list price for PNH, it might be argued that the effective price paid in Canada by government payors is "non-excessive" relative to international comparator prices. However, it should be noted that given the excessive pricing for Soliris, governments in other countries, including drug plans in the United Kingdom, Ireland and New Zealand, have also resorted to negotiations with the Respondent. The Respondent would be the best source to confirm other comparator countries with whom it has negotiated lower non-transparent prices. The following media articles (links below) provide some indication of the countries where such negotiations have been completed.

http://www.pharmaphorum.com/articles/soliris-the-worlds-most-expensive-drug-will-nice-judge-it-affordable, http://www.irishtimes.com/news/health/how-can-the-hse-put-a-price-on-your-life-1.2053192, http://tvnz.co.nz/national-news/pharmac-willing-negotiate-life-saving-treatment-5324999

14. The public list price is also an important reference point for other public drug coverage policies. In addition to the drug ingredient cost, provincial governments also pay mark-ups or other professional fees to pharmacies as part of their remuneration to supply drugs to patients. Currently mark-up fees payable by provincial governments are calculated as a percentage of the drug ingredient costs based upon the public list price. The fees are typically in the 6-10% range, but may be as high as 30% (Yukon). In the case of Soliris, a mark-up fee of 8% would add more than $42,000 annually to the overall cost of the drug for each PNH patient funded. To assist in managing the potential amount of the mark-up, jurisdictions may use various strategies to avoid or minimize paying the mark-up on Soliris, such as through capitation policies.

15. In 2013, the CDR's advisory committee, now known as the Canadian Drug Expert Committee ("CDEC"), recommended that Soliris not be listed for treatment of aHUS. In making those recommendations, the Committee stated that the "two uncontrolled prospective studies had several important limitations. Therefore the clinical benefit of eculizumab could not be adequately established." Attached to this my Affidavit and marked as Exhibit B is a copy of the CDEC's Recommendation on Soliris for aHUS. The public drug plans are currently seeking advice from CDEC regarding the use of Soliris in aHUS. Attached to this my Affidavit and marked as Exhibit C is a copy of the Canadian Agency for Drugs and Technology in Health Common Drug Review Submission Status document confirming the request for advice.

16. Because of the 2013 CDEC "do not list" recommendation for aHUS, the provinces and territories have not negotiated for a confidential lower price for use of Soliris in aHUS. As such, if a province or territory chooses to cover a patient for an indication other than PNH on an exceptional basis, that jurisdiction will be required to pay the full list price of the product (unless some other agreement has been made between that jurisdiction and the manufacturer).

17. Although provincial governments pay for a significant proportion of Soliris treatments, there are other payors as well – hospitals (which may provide funding independently of public drug plans), drug benefit insurers and private payors. These payors are not able to benefit from any negotiated agreements that the provincial governments may have with the Respondent. These other payors would need to pay the full list price of the product unless there was an agreement in place between the payor and the Respondent. For example, I am aware of a Vancouver hospital in BC that pays the full list price of the product plus 5% mark-up for a patient; this was a funding decision made independently from the Ministry of Health.

18. The Ministry of Health and the Represented Jurisdictions respectfully request that in making its decision, the Board consider the significant challenges that provincial governments face as a result of the pricing of Soliris.

19. The Ministry of Health and the Represented Jurisdictions respectfully request that the Board:

(a) order the Respondent to reduce the price of Soliris to match the lowest price for Soliris among all comparator countries effective within 30 days of the date of the Board's Order, and

(b) order that the Respondent offset the cumulative revenues it has received during the period of January 1, 2012 to the effective date of the Board's Order noted in (a) by making a payment to Her Majesty in Right of Canada, within 30 days of the Board's order, in an amount that is equal to the excess revenues the Board estimates that the Respondent has generated from the sale of Soliris at an excessive price, using the lowest price for Soliris among all comparator countries as the reference for the appropriate price for the product.

20. I swear this affidavit in support of the request of the Ministry of Health and the Represented Jurisdictions for the remedy set out above.

SWORN BEFORE ME)
at Victoria, British Columbia)
on April 1, 2015.)
Original signature redacted)
)
A commissioner for taking)
affidavits for British Columbia)

SHARNA KRAITBERG
Barrister and Solicitor

Original signature redacted

Eric Lun

This is Exhibit A
referred to in the Affidavit
of ERIC LUN
sworn before me this 1ST day
of April , 2015
Orig. sig. redacted
A Commissioner for taking Affidavits
within British Columbia

CEDAC FINAL RECOMMENDATION

ECULIZUMAB
(Soliris – Alexion Pharmaceuticals, Inc.)
Indication: Paroxysmal Nocturnal Hemoglobinuria

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that eculizumab not be listed at the submitted price.

Reason for the Recommendation:
In the one double-blind randomized controlled trial included in the CDR systematic review, a clinically and statistically significant reduction in hemolysis was observed for eculizumab compared with placebo. The cost of eculizumab is exceptionally high at over $500,000 per year. Eculizumab would not be considered cost-effective without a substantial reduction in the submitted price. The CDR estimated an incremental cost per quality-adjusted life-year of $2.4 million for eculizumab plus supportive care compared with supportive care alone based on 26 week trial data where quality of life benefits for a lifetime condition may not have been fully captured.

Of Note:
Using conventional criteria, eculizumab has not been shown to be cost-effective, though cost-effectiveness is only one factor that is used by drug plans in making funding decisions. It has been argued that the costs of drugs to treat rare diseases are often high because of the relatively small number of patients for whom the drug is indicated.

Background:
Eculizumab has a Health Canada indication for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. It is a monoclonal antibody that binds to complement protein C5, thereby inhibiting terminal complement-mediated intravascular hemolysis.

The Health Canada recommended dose of eculizumab is 600 mg given intravenously (IV) once weekly for four weeks, then 900 mg IV at week five, followed by 900 mg IV every 14 days as a maintenance dose. It is supplied as a 300 mg single-use vial containing 10 mg/mL of preservative-free eculizumab solution for intravenous infusion.

Patients with PNH have a genetic mutation that results in the lack of expression of glycosylphosphatidylinositol (GPI) anchor proteins on blood cells. This leads to the clonal expansion of abnormal blood cells that are susceptible to terminal complement-mediated destruction, leading to intravascular hemolysis. These blood cells, or clones, are categorized as normal (type I), partially GPI-deficient (type II), and completely GPI-deficient (type III). PNH is a non-malignant condition and may result in shortened survival and significant morbidity, including thrombosis, cytopenias, end-organ damage, reduced quality of life, and fatigue. Therapeutic management primarily consists of supportive care, which includes blood transfusions and medications, such as anticoagulants, corticosteroids, and immunosuppressants. Bone marrow transplantation may also be considered a treatment option for some patients. Eculizumab therapy would be continued long term.

Summary of CEDAC Considerations:
The Committee considered the following information prepared by the Common Drug Review (CDR): a systematic review of randomized controlled trials (RCTs) and open-label, non-randomized studies of eculizumab that included 10 or more patients as well as an assessment of manufacturer-provided pharmacoeconomic information. A priority review of this submission was requested by the manufacturer and granted by CDR.

Clinical Trials
The CDR systematic review included one manufacturer-sponsored, double-blind RCT, and three open-label non-randomized manufacturer-sponsored trials of eculizumab. The Committee's discussion focused on the results from the RCT.

The double-blind RCT, TRIUMPH (N = 87), evaluated the efficacy of eculizumab compared with placebo given for 26 weeks to patients with PNH. Eculizumab was administered IV with an induction dose of 600 mg every seven days for four weeks, then a 900 mg dose seven days later on week five, followed by 900 mg every 14 days thereafter.

TRIUMPH included patients who had required four or more transfusions in the 12 months prior to study enrolment, and a minimum platelet count of ≥ 100,000 cells/mm^3. Patients were stratified by the number of transfusions required at baseline. Patients were required to be vaccinated with *Neisseria meningitidis* vaccine at least 14 days before initiating eculizumab. Stable doses of concomitant medications were allowed (anticoagulants, systemic corticosteroids, androgen steroids, immunosuppressants, erythropoietin, and iron and folate supplements). Because changes in medications were not permitted, the impact of eculizumab on supportive therapy is unknown. Study withdrawals were low, with 98% (85 of 87) of patients completing the study.

The three non-randomized studies were all open-label prospective, manufacturer-sponsored trials:

- The SHEPHERD study (N = 97) was a multinational before and after long-term safety study evaluating eculizumab over 52 weeks. SHEPHERD included a broader population of patients with PNH compared with TRIUMPH, including patients with minimal transfusion requirements and those with thrombocytopenia.
- Study C02-001 (N = 11) examined the tolerability, efficacy, pharmacokinetics, and pharmacodynamics of eculizumab. Patients who completed the initial 12-week treatment were eligible for subsequent extension phases up to 104 weeks.

- Study C07-001 (N = 29) is an unpublished study evaluating eculizumab over 12 weeks in Japanese patients with PNH. The inclusion criteria were similar to those of the SHEPHERD trial.

Open-label extension phases of these studies were also reviewed, including Study E05-001 (N = 195, up to 104 weeks), which evaluated the long-term harms of eculizumab in patients with PNH who participated in TRIUMPH, SHEPHERD, and Study C02-001.

The proportion of type III red blood cell clones in patients at baseline was generally greater than 30% in all four studies. The median proportion in TRIUMPH was 28.9% and 32.9% in eculizumab and placebo groups respectively. In the non-randomized studies, the median proportion ranged from 33.5% to 39.2%.

Outcomes

The two primary outcomes of the TRIUMPH study were the stabilization of hemoglobin levels (defined as a hemoglobin value maintained above the level at which transfusion was required) and the number of packed red blood cell units transfused during the 26-week study period. The primary end point of the SHEPHERD study and Study C07-001 was hemolysis as measured by lactate dehydrogenase (LDH). The primary outcome of Study C02-001 was not specified.

Other key outcomes were defined a priori in the CDR systematic review protocol. Of these, the Committee discussed the following: thrombotic events; transfusion avoidance; the proportion of PNH type III red blood cell clones; quality of life, including changes in fatigue levels; serious adverse events; and adverse events.

Quality of life was assessed using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) scale and the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) as general composite measures.

TRIUMPH was not designed to detect an effect of eculizumab on survival or on the incidence of thrombotic events, which is the strongest risk factor for death in patients with PNH.

Results

Efficacy or Effectiveness

- In the TRIUMPH study, eculizumab resulted in a statistically significant reduction in hemolysis as measured by LDH when compared with placebo. A statistically significant increase in the proportion of patients achieving transfusion avoidance was also observed, favouring eculizumab.
- In the TRIUMPH study, hemoglobin stabilization was achieved in 49% of patients treated with eculizumab and in none of the placebo patients ($P < 0.001$), indicating that these patients did not require any transfusions during the 26-week study. A statistically significant reduction in the number of packed red blood cell units transfused was also achieved in the eculizumab group compared with the placebo group.
- Eculizumab-treated patients showed statistically significant improvements in quality of life compared with placebo-treated patients, using the FACIT-Fatigue scale and the majority of the EORTC subscales.
- In the TRIUMPH study, there were no thrombotic events in the eculizumab group, and one in the placebo group despite anticoagulation. Analysis of combined extension study data

from the TRIUMPH, SHEPHERD, and C02-001 studies were suggestive of a significant reduction in thrombotic event rates; however, limitations associated with retrospective data collection and non-randomized studies limit the scientific validity of these data.
- Data on hemoglobin stabilization, transfusion requirements, hemolysis, and quality of life from the three non-randomized studies were supportive of findings from the TRIUMPH study.

Harms (Safety and Tolerability)
- No deaths occurred in the TRIUMPH study, and serious adverse events, adverse events, and withdrawals due to adverse events were similar between eculizumab and placebo. The most common serious adverse events across all studies included breakthrough exacerbations of PNH, hemolysis, anemia, and infections. The most common adverse events reported in all the studies were headache and nasopharyngitis.
- There is a theoretical possibility of a rebound effect upon discontinuation of eculizumab. This is currently being monitored and no cases have been identified to date, although in [redacted] patients in whom eculizumab infusion was [redacted], [redacted], severe [redacted] was reported.
- A smaller proportion of eculizumab patients compared with placebo patients had a serious infection in the TRIUMPH trial (2.3% versus 9.1% respectively). Similarly the proportion of patients reporting serious infections was low in the non-randomized studies, ranging from 3% to 9% across studies. Data on infections may be confounded by concomitant use of corticosteroids and immunosuppressant agents, especially in the uncontrolled trials.
- No cases of meningococcal infection were reported in the included studies but, to date, [redacted] cases of meningococcal infection have been reported in patients receiving eculizumab (three in clinical trials and [redacted] from post-marketing surveillance). Vaccination was confirmed in two of the three cases reported in clinical trials. One infection was due to [redacted], for which no vaccine exists.

Cost and Cost-Effectiveness
The annual cost of eculizumab is $539,360 in the first year and $525,876 in subsequent years, based on recommended doses.

CDR provided information on potential cost offsets and benefits in quality of life for eculizumab. Quality of life was felt to be an important consideration given the fatigue associated with PNH, the time required to obtain blood transfusions, and the risks of transfusion-related complications. Quality of life information (EORTC scores) from the TRIUMPH trial was used to estimate utility scores for eculizumab plus supportive care and for supportive care alone, based on an algorithm validated in patients with esophageal cancer. Costs were based on the cost of eculizumab (at 26 weeks to reflect the TRIUMPH trial period) and it was assumed that no treatment was associated with zero costs. Potential cost offsets, such as thrombotic events avoided, tended to be small in comparison with the cost of eculizumab. CDR estimated that the incremental cost per quality-adjusted life-year of eculizumab plus supportive care was $2.4 million compared with supportive care alone, based on short-term trial data (26 weeks) where quality of life benefits for a lifetime condition may not have been fully captured. Consideration of longer-term benefits would reduce the incremental cost per quality-adjusted life-year, but not to an amount below $500,000.

Other Discussion Points:

- The incidence and prevalence of PNH were discussed, as well as the range of these estimates and the proportion of patients with symptomatic and asymptomatic PNH.
- The variability in definitions of rare disease was discussed by the Committee.
- The likelihood of patients discontinuing anticoagulation therapy while receiving eculizumab was discussed. The product monograph notes that the effect of withdrawing anticoagulation therapy during treatment with eculizumab has not been established, therefore, treatment with eculizumab should not change anticoagulant management.
- TRIUMPH was not designed to detect an effect of eculizumab on survival or on the incidence of thrombotic events, which is an important prognostic factor for survival in PNH.
- It was noted that the mechanism of action of eculizumab is to inhibit the complement cascade, which places patients at an increased risk of infection, particularly by *Neisseria* organisms including *N. meningitides*, and likely other encapsulated organisms.
- The importance of type III clones was discussed by the Committee. High proportions of type III clones, when considered along with other clinical factors, are associated with an increased likelihood of hemolysis and thrombotic events.
- The Committee discussed whether or not a subgroup of patients could be identified that would be expected to experience greater benefit from eculizumab, but could not identify such a subpopulation in the included studies.
- Differences between treatment groups with respect to baseline characteristics, such as disease duration, platelet count, and secondary causes were discussed. The Committee considered that the hemolysis effect size was large enough to overcome these potential biases and noted the difficulty in balancing baseline characteristics in trials with small sample sizes and in a heterogeneous condition such as PNH.
- The role of bone marrow transplantation, which is potentially curative in treating certain subtypes of PNH, was discussed. Bone marrow transplantation is usually only reserved for severely ill PNH patients.
- In the six-month reporting period of a recent Periodic Safety Update Report, [redacted] patients were exposed to eculizumab, but not all had [redacted]. Eculizumab is currently being evaluated for other indications.

CEDAC Members Participating:

Dr. Robert Peterson (Chair), Dr. Anne Holbrook (Vice-Chair), Dr. Michael Allan, Dr. Ken Bassett, Dr. Bruce Carleton, Dr. Doug Coyle, Mr. John Deven, Dr. Alan Forster, Dr. Laurie Mallery, Mr. Brad Neubauer, Dr. Lindsay Nicolle, Dr. Yvonne Shevchuk, and Dr. Kelly Zarnke.

Regrets:

None

Conflicts of Interest:

CEDAC members reported no conflicts of interest related to this submission.

About this Document:
CEDAC provides formulary listing recommendations to publicly funded drug plans. Both a technical recommendation and plain language version of the recommendation are posted on the CADTH website when available.

CDR clinical and pharmacoeconomic reviews are based on published and unpublished information available up to the time that CEDAC made its recommendation.

The manufacturer has reviewed this document and has requested the removal of confidential information in conformity with the CDR Confidentiality Guidelines.

The Final CEDAC Recommendation neither takes the place of a medical professional providing care to a particular patient nor is it intended to replace professional advice.

CADTH is not legally responsible for any damages arising from the use or misuse of any information contained in or implied by the contents of this document.

The statements, conclusions, and views expressed herein do not necessarily represent the view of Health Canada or any provincial, territorial, or federal government or the manufacturer.

This is Exhibit B
referred to in the Affidavit
of ERIC LON
sworn before me this 1ST day
of April , 2015
Orig. sig. redacted
A Commissioner for taking Affidavits
within British Columbia

CDEC FINAL RECOMMENDATION

ECULIZUMAB
(Soliris — Alexion Pharmaceuticals Inc.)
New Indication: Atypical Hemolytic Uremic Syndrome

Recommendation:
The Canadian Drug Expert Committee (CDEC) recommends that eculizumab not be listed.

Reasons for the Recommendation:
Two uncontrolled prospective studies had several important limitations, including a lack of clear diagnostic criteria for atypical hemolytic uremic syndrome (aHUS), the absence of a comparator group to examine outcome differences, short duration of follow-up, and lack of data regarding clinically important outcomes for patients with aHUS. Therefore, the clinical benefit of eculizumab could not be adequately established.

Background:
Eculizumab has a Health Canada indication for the treatment of patients with aHUS to reduce complement-mediated thrombotic microangiopathy (TMA). Eculizumab has been issued a marketing authorization without conditions for adults and adolescents aged 13 to 17 years, weighing more than 40 kg who have aHUS. In children less than 13 years of age and/or weighing less than 40 kg, eculizumab has been issued a marketing authorization with conditions (i.e., Notice of Compliance with Conditions), pending the results of studies to verify its clinical benefit.

Following an induction phase of 900 mg weekly for four weeks and 1,200 mg at week five, the recommended maintenance dosage is 1,200 mg every two weeks. Children weighing less than 40 kg are dosed according to weight. A supplemental eculizumab dose is administered when plasma therapy (PT) is required. Eculizumab is available as a 10 mg/mL solution for intravenous injection.

Submission History:
Eculizumab was previously reviewed by the Canadian Expert Drug Advisory Committee (CEDAC) for paroxysmal nocturnal hemoglobinuria to reduce hemolysis; it received a recommendation that it "not be listed at the submitted price" (see Notice of CEDAC Final Recommendation, February 19, 2010).

Summary of CDEC Considerations:
CDEC considered the following information prepared by the Common Drug Review (CDR): a systematic review of eculizumab trials, a critique of the manufacturer's pharmacoeconomic evaluation, and patient group-submitted information about outcomes and issues important to patients.

Patient Input Information
The following is a summary of information provided by one patient group that responded to the CDR call for patient input:

- Patients with aHUS report high amounts of emotional, financial, and responsibility-related stress leading to feelings of isolation, fear, hopelessness, anxiety, and depression.
- PT causes increased fatigue, confused thinking, and nausea post-treatment, and patients experience high total protein levels, increased blood pressure, and headaches. PT is only available in major hospitals; therefore, many patients must travel for treatment, which increases time and financial burdens on families. Parents of patients undergoing PT estimated that their children miss 30% to 40% of their school year, with the parent having 20% to 40% absenteeism from work.
- Patients indicated that treatment with eculizumab would not require the use of a central line and would allow them to avoid attending weekly or biweekly plasma infusions, which can last upwards of seven hours.

Clinical Trials
There were no randomized controlled trials (RCTs) identified in the CDR systematic review; therefore, the review included three uncontrolled, manufacturer-sponsored studies conducted in patients with a diagnosis of aHUS, with or without identified gene mutations. Studies C08-002 (N = 17) and C08-003 (N = 20) were phase 2, prospective, multicentre, single-arm, open-label trials conducted in adults and adolescents ages 12 to 17 years. The study medication was administered for 26 weeks. Study C09-001 was a retrospective chart review of 30 patients that included children (0 to 11 years), adolescents (12 to 17 years), and adults. In study C08-002, patients were included if they were intolerant to PT or were resistant to PT, despite four or more treatments in the week before the start of study treatment. In study C08-003, patients were included if they were PT sensitive and had stable platelet counts during PT treatment. In study C09-001, both PT-resistant and PT-sensitive patients were considered for inclusion.

The trials included North American and European patients. The prospective trials were mainly conducted in adults (median 28 years) with more than 60% of patients being women; whereas, 50% of the patients in the retrospective chart review were children younger than 12 years, with an equal proportion of males and females. In studies C08-002 and C09-001, 40% of patients were experiencing their first attack of aHUS; whereas, in study C08-003, 25% of patients were experiencing a first attack. In studies C08-002 and C08-003, 35% and 10% of patients had received dialysis within the two months before eculizumab treatment respectively. In study C09-001, 37% of patients had at least gone through one dialysis session. Approximately 40% of patients had received a kidney transplant across all trials.

Outcomes

Outcomes were defined a priori in the CDR systematic review protocol. Of these, CDEC discussed the following:

- Mortality — a safety endpoint in the included studies.
- PT-free status — the number of PT sessions before and during eculizumab therapy.
- Dialysis-free status — the number of dialysis events before and during eculizumab therapy.
- Health-related quality of life (HRQoL) — measured with the European Quality of Life Scale (EuroQol-5D time trade off index and the visual analogue scale [VAS]).
- TMA event-free status — absence of the following three events: decrease in platelet count of > 25% from baseline; PT while patient is receiving study drug; and new dialysis.
- Complete TMA response — defined as hematologic normalization and 25% reduction from baseline in serum creatinine.
- Hematologic normalization — normalization of both platelet count and lactate dehydrogenase.
- Chronic kidney disease (CKD) stage — improvement by at least one CKD stage.
- Serious adverse events, adverse events, and withdrawals due to adverse events.

The primary end points were platelet count change (C08-002) and the proportion of patients who achieved TMA event-free status (C08-003). If statistically significant, then a second primary end point, the proportion of patients who achieved hematologic normalization, was evaluated.

Results

Efficacy

- There were no deaths in study C08-002 or C08-003 and two patients died in C09-001.
- All but one patient discontinued PT while on eculizumab treatment in the prospective trials (C08-002 and C08-003). In study C09-001, 30% of patients continued to receive PT while on eculizumab.
- In study C08-002, patients who had required dialysis pre-eculizumab (35%) were able to discontinue dialysis during eculizumab treatment, and one patient who was dialysis-free before eculizumab treatment required dialysis while on the study drug. In study C08-003, two patients who had received dialysis before eculizumab therapy were unable to discontinue dialysis during treatment with eculizumab. There were no new dialysis cases in study C08-003. In study C09-001, patients who had received dialysis were able to discontinue dialysis while on eculizumab treatment. There were two new dialysis patients during the treatment period of study C09-001.
- Patients' HRQoL was improved in both prospective trials; improvements were greatest in PT-resistant/intolerant patients (study C08-002). Some PT-sensitive patients (study C08-003) experienced deterioration in the HRQoL score while on eculizumab treatment.
- In studies C08-002, C08-003, and C09-001, 88%, 80%, and 57% of patients (respectively) were TMA event-free.
- In studies C08-002 and C08-003, 65% and 25% of patients (respectively) experienced a complete TMA response. TMA response was sustained for a mean of 120 days (standard deviation [SD] 49) in study C08-002 and for a mean of 80 days (SD 40) in study C08-003.
- In studies C08-002 and C08-003, 76% and 90% of patients (respectively) experienced a normalization of platelet count and lactate dehydrogenase level during the treatment period.
- In studies C08-002, C08-003, and C09-001, 59%, 35%, and 40% of patients (respectively) improved by at least one stage in CKD; 65%, 15% and 40% of patients (respectively) had a

decrease of ≥ 25% in serum creatinine level; and 47%, 5% and 37% of patients (respectively) improved by ≥ 15 mL/minute/1.73 m^2 in estimated glomerular filtration rate (eGFR).

Harms (Safety and Tolerability)

- Almost every patient in the prospective trials experienced at least one adverse event (97%); whereas, in the retrospective chart review, 73% of patients reported having at least one adverse event.
- The most common adverse events were hypertension (47%), headache (41%), and anemia (35%) in study C08-002; upper respiratory tract infection (40%) and hypertension (25%) in C08-003; and pyrexia (30%) and cough (23%) in C09-001. In all three trials, patients experienced diarrhea (27% to 35%) and vomiting (15% to 29%).
- Fifteen patients (88%) and five patients (25%) reported at least one serious adverse event in studies C08-002 and C08-003 respectively.
- In studies C08-002 and C08-003, there were 38 episodes of infection. Five infections were considered serious, for which patients required hospitalization.
- A total of 35% of patients experienced at least one hypertension-related event including six serious adverse events.
- One patient experienced gastrointestinal bleeding that was deemed to be possibly related to eculizumab treatment (study C08-003).
- One patient withdrew from study C08-002 due to an adverse event.

Cost and Cost-Effectiveness

The manufacturer submitted an economic analysis comparing eculizumab plus non-biologic supportive care (excluding plasma exchange) with non-biologic supportive care (including plasma exchange) over a one-year time horizon, where supportive care included dialysis and supportive care treatment for end-stage renal disease, hospitalization, and physician consults. Due to a dearth of information available for the management of patients with aHUS, the manufacturer consulted five Canadian experts with an interest in aHUS to identify all relevant health care resources for the management of patients with aHUS, and the expected frequency of use. The manufacturer reported the annual cost per patient of treatment with eculizumab plus non-biologic supportive care (excluding plasma exchange) to be $746,899 in the first year, compared with a cost of $210,056 for treatment with plasma exchange plus non-biologic supportive care.

A number of limitations were noted with the economic submission:

- Quality of life information was collected in the eculizumab clinical trial, which could have been used to present a more informative cost-utility analysis to examine the relative cost-effectiveness of eculizumab in patients with aHUS.
- The difficulty in diagnosing aHUS in patients may substantially inflate the total cost of treatment (budget impact) for public plans due to the extremely high price of eculizumab.
- The eculizumab product monograph indicates that treatment should not be stopped once initiated. Thus, the cost of eculizumab treatment would be incurred for the remainder of the patient's life, the length of which is unknown as there is no reliable data indicating the life expectancy of a patient with aHUS, before or after treatment with eculizumab.

- The estimates of cost and duration of plasma exchange, which drive non-biologic supportive care, are highly uncertain; this then has an impact on the determination of the assessment of incremental cost for eculizumab.
- No information was presented to assess the efficacy of the PT.
- Eculizumab may be used in combination with plasma exchange, which was not accounted for in the manufacturer's economic submission. The CDR re-analysis showed that concomitant treatment would greatly increase the incremental cost of treatment of eculizumab up to $940,084 per patient per year.

The annual drug cost per patient for eculizumab treatment ranges from $121,356 to $728,136, depending on the weight of the patient. The annual incremental cost of eculizumab treatment may lie between $500,000 and $600,000 per patient compared with non-biologic supportive care plus plasma exchange; however due to the paucity of data, there is considerable uncertainty with this estimate.

Other Discussion Points:
CDEC noted the following:

- Eculizumab was evaluated in a broad selection of patients with aHUS, including both PT-resistant and PT-sensitive patients, patients with first and subsequent episodes of aHUS, those with and without genetic mutations, patients with or without kidney transplants, and patients with and without a history of dialysis. Despite subgroup analyses conducted for the prospective trials, the small number of patients included prevented the identification of subpopulations that are most likely to benefit from eculizumab therapy.
- Given that the studies included in the CDR review were uncontrolled and of short duration, the impact of eculizumab on the development of renal complications and mortality is unclear.
- Baseline EQ-5D scores were higher than might be expected for a severe disease, including 11 patients who reported a score of 0.94, which could make assessing improvements difficult due to a ceiling effect.
- The included studies mainly enrolled adults and a few adolescents; therefore, a formal evaluation in pediatric patients would be beneficial.
- There are limited data for use of eculizumab in children (< 12 years) with aHUS.
- Limitations of currently available diagnostics have the potential to result in their use where there is suspicion but not confirmation of aHUS, with significant cost consequence.

Research Gaps:
CDEC noted that there is insufficient evidence regarding the following:

- Efficacy and safety of eculizumab in children (< 12 years) with aHUS.
- Clinical benefit of eculizumab on overall survival for patients with aHUS.
- Clinical indicators of therapeutic failure for patients treated with eculizumab.
- Effect of eculizumab on hemoglobin levels in the absence of treatment with erythropoietin.
- Relative benefit of eculizumab in relation to PT.
- Subgroups likely to respond or need ongoing therapy.

CDEC Members:
Dr. Robert Peterson (Chair), Dr. Lindsay Nicolle (Vice-Chair), Dr. Ahmed Bayoumi, Dr. Bruce Carleton, Ms. Cate Dobhran, Mr. Frank Gavin, Dr. John Hawboldt, Dr. Peter Jamieson, Dr. Julia Lowe, Dr. Kerry Mansell, Dr. Irvin Mayers, Dr. Yvonne Shevchuk, Dr. James Silvius, and Dr. Adil Virani.

June 19, 2013 Meeting

Regrets:
None

Conflicts of Interest:
None

About This Document:
CDEC provides formulary listing recommendations or advice to CDR participating drug plans. CDR clinical and pharmacoeconomic reviews are based on published and unpublished information available up to the time that CDEC deliberated on a review and made a recommendation or issued a record of advice. Patient information submitted by Canadian patient groups is included in the CDR reviews and used in the CDEC deliberations.

The manufacturer has reviewed this document and has not requested the removal of confidential information in conformity with the *CDR Confidentiality Guidelines*.

The CDEC recommendation or record of advice neither takes the place of a medical professional providing care to a particular patient nor is it intended to replace professional advice.

CADTH is not legally responsible for any damages arising from the use or misuse of any information contained in or implied by the contents of this document.

The statements, conclusions, and views expressed herein do not necessarily represent the view of Health Canada or any provincial, territorial, or federal government or the manufacturer.

This is Exhibit C
referred to in the Affidavit
of Eric Lun
sworn before me this 1st day
of April , 2015
Orig. sig. redacted
A Commissioner for taking Affidavits
within British Columbia

CADTH

Common Drug Review

Submission Status

Product: Soliris
Generic Name: eculizumab
Manufacturer: Alexion Pharma Canada
Indication: Hemolytic Uremic Syndrome, Atypical
Submission Type: Request for Advice
Date Submission Received: 2015-Feb-09
Date NOC Issued: 2013-Mar-01
Original Targeted CDEC Meeting: 2015-May-20

Key Milestone[1]	Target Date	Actual CDR Date	Comments
CADTH request for advice approach detemined	2015-Feb-24	2015-Feb-24	- 2015-Feb-09: Manufacturer informed of request for advice - Information or comments due 2015-Feb-24 - Manufacturer information/comments received: 2015-Feb-24 - Review has been initiated 2015-Feb-25
Draft CDR Request for Advice report sent to manufacturer	2015-Apr-13		
Comments from manufacturer on draft CDR Request for Advice report received by CADTH	2015-Apr-22		
Redaction response from manufacturer on draft CDR Request for Advice report received by CADTH	2015-Apr-29		
CDEC meeting	2015-May-20		
If the request for advice does not result in a new or revised CDEC recommendation: CDEC Record of Advice sent to drug plans and manufacturer			
CDEC Record of Advice report posted[3]			
CDR Request for Advice report posted[3]			
OR			
If the request for advice results in a new or revised CDEC recommendation: CDEC recommendation & redacted CDR Request for Advice report sent to drug plans and manufacturer			
Embargo period[2] and validation of redacted CDR Request for Advice report Manufacturer may make a request for reconsideration and drug plans may make a request for clarification of the recommendation			
CDEC Final Recommendation sent to drug plans and manufacturer (No request for clarification is made AND no request for reconsideration is made or request for reconsideration is resolved)			
CDEC Final Recommendation posted [3]			
Final CDR Request for Advice report posted [3]			
OR			
Clarification and final recommendation sent to drug plans and manufacturer (Clarification requested, no request for reconsideration made)[4]			
CDEC Final Recommendation posted [3]			
Final CDR Request for Advice report posted [3]			
OR			
Placed on CDEC agenda for reconsideration (At manufacturer's request)[4]			
CDEC Final Recommendation sent to drug plans and manufacturer			
CDEC Final Recommendation posted [3]			
Final CDR Request for Advice report posted [3]			

[1] Please refer to the *Procedure for the CADTH Common Drug Review* in the Common Drug Review section of www.cadth.ca for complete details regarding the CDR request for advice process and targeted time frames for key milestones.

[2] The recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of final recommendation. A manufacturer may request an extension of up to 20 extra business days solely for the purpose of preparing and filing a request for reconsideration (i.e., a total of 30 business days)

[3] The target date for posting a CDEC Record of Advice, the CDEC Final Recommendation and CDR Request for Advice report depends on several factors including the need for consultation with the manufacturer regarding redaction issues.

[4] The time frame required to address a request for clarification at the drug plans' request or request for reconsideration at the manufacturer's request depends on the amount of work required to address the request and the available dates for CDEC meetings.

This submission status report typically reflects status as of Thursday noon Eastern Time.

THIS IS **EXHIBIT "J"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.

ALAN WEST

PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act*,
R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. (the "Respondent")
and the medicine "Soliris"

REPLY TO THE RESPONDENT'S RESPONSE TO BOARD STAFF'S STATEMENT OF ALLEGATIONS

1. Board Staff repeats and relies on its Statement of Allegations and the defined terms contained therein.

2. Board Staff admits paragraphs 3 and 5 of the Response. Board Staff alleges that Alexion's National Average Transaction Price ("**N-ATP**") in Canada, which is the same as its publicly available list price, is excessive over a three-year period beginning in 2012; and that Alexion has not increased (or reduced) the publicly available list price of Soliris since it was introduced.

3. Board Staff has no knowledge of the actual ex-factory prices of Soliris in any of the comparator countries referenced in paragraphs 6 and 7 of the Response. Board Staff's investigation into the price of Soliris compared the N-ATP with the publicly available list prices in each of the comparator countries, as alleged in paragraph 15 of the Statement of Allegations.

4. Board Staff denies the balance of the allegations contained in the Response generally and more specifically as set out below. Board Staff further asserts that the majority of Alexion's allegations in paragraphs 8 to 27 are arguments, not material facts. In any case, Board Staff disagrees with these arguments.

5. Board Staff denies paragraph 8 of the Response. Board Staff did not conclude that the introductory price of Soliris was "non-excessive". Alexion deliberately chose to price Soliris at introduction above the ceiling price set by the Maximum Non-Excessive Price ("**MNE**") (now the Maximum Average Potential Price "**MAPP**") under the Board's then Guidelines. The MNE was set by the median international price among the comparator countries, which is a premium ceiling price only afforded to medicines that are breakthrough or of substantial therapeutic improvement. As Alexion is aware, Board Staff determined that Alexion's introductory price of Soliris exceeded the median international price among the comparator countries; however, the excess revenues Alexion generated did not meet the criteria for continuing the investigation. These criteria were established to allow Board Staff to allocate its resources to investigations as efficiently as possible. In deciding not to pursue the investigation, Board Staff did not therefore deem the introductory price of Soliris to be "non-excessive".

6. Contrary to paragraphs 8 and 9 of the Response, Board Staff has not alleged that the price of Soliris is excessive due to changes in exchange rates. Board Staff submits that based on the factors under subsection 85(1) of the Act, the Regulations and the Board's Guidelines, Alexion has been selling Soliris to

Canadians at an excessive price since 2012. Board Staff further submits that its application of the factors, the Regulations and the Board's Guidelines in this case is appropriate and reasonable.

7. Board Staff denies paragraph 10 of the Response. Alexion requested particulars that were both within its knowledge and not required to enable it to plead. Alexion does not therefore require particulars. A copy of Alexion's request and Board Staff's response is attached at Appendix A and B respectively.

8. Board Staff denies paragraphs 11 and 12 of the Response. Board Staff submits that the Highest International Price Comparison ("**HIPC**") test, which is long-established and the result of extensive consultation with stakeholders, is a generous application of paragraph 85(1)(c) of the Act. It targets those extreme cases where the Canadian price of a patented medicine not only exceeds the international median but the prices in all other comparator countries listed in the Regulations.

9. The exchange rate methodology used to compare prices in Canada with those in the comparator countries is also long-established and the result of extensive consultation with stakeholders. The methodology uses the simple average of the thirty-six monthly average noon spot exchange rates, as published by the Bank of Canada, to convert international prices to prices in Canadian dollars. The thirty-six month period, among other things, provides predictability to patentees, reduces short term volatility without insulating the international price comparison from long term trends in international currency relationships, and is not inherently

biased in favour of the patentee or consumers. It is also the same methodology that is used to calculate the MAPP or the ceiling price at introduction under the Board's Guidelines. The methodology allows for meaningful international price comparisons so that the extreme cases where the Canadian price exceeds the price in all other comparator countries may be identified.

10. Board Staff denies paragraph 13 of the Response. Board Staff asserts that at all material times Alexion knew or ought to have known that its decision to set the Canadian price for Soliris — for which there are no domestic comparators — above the international median and among the highest international prices of the comparator countries may result in the price of Soliris contravening the Act. Moreover, Alexion has deliberately chosen not to reduce the price of Soliris in Canada since it became the highest international price among the comparator countries at least three years ago.

11. Further, contrary to Alexion's allegation in the last sentence of paragraph 13 of the Response, Board Staff is not required under the Act to demonstrate that any consumer is "worse off" as a result of Alexion's pricing decisions. In any case, Canadians are harmed by the excessive price of Soliris.

12. Board Staff denies paragraph 14 of the Response. Board Staff did not make any errors in concluding that the price of Soliris has been excessive since 2012.

13. Board Staff denies Alexion's economic arguments at paragraphs 15 to 26 of the Response. The Act requires that the Board must consider "the prices at which

the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada." If accepted, Alexion's economic arguments would mean that no comparisons between Canadian and foreign prices could be made under subsection 85(1)(c) of the Act, thus rendering the statutory factor meaningless.

14. Board Staff denies paragraph 19 of the Response. Patentees are not entitled to price increases under the Act. A patentee's choice not to increase the price of its medicine does not make the price of the drug "non-excessive". In this case, had Alexion increased the price of Soliris in Canada, it would have generated even greater excess revenues.

15. Board Staff denies paragraphs 26 and 27 of the Response. The purpose of the relevant provisions of the Act is to protect Canadians by ensuring that the prices of patented medicines in Canada are not excessive.

16. Board Staff denies paragraphs 28, 29 and 30 of the Response. Board Staff has not made any factual errors in its Statement of Allegations.

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Parul Shah
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David Migicovsky
Email: dmigicovksy@perlaw.ca

Christopher Morris
Email: cmorris@perlaw.ca

Lawyers for Board Staff

APPENDIX A

12 February 2015

Malcolm N. Ruby
Direct 416-862-4314
Direct Fax 416-863-3614
malcolm.ruby@gowlings.com
File No. T999663

VIA E-MAIL: CMorris@perlaw.ca

Christopher P. Morris
Perley-Robertson, Hill & McDougall LLP
340 Albert Street
Suite 1400
Ottawa, Ontario
K1R 0A5

Dear Mr. Morris:

Re: IN THE MATTER OF the *Patent Act*, R.S.C. 1985, c. P-4, as amended AND IN THE MATTER OF Alexion Pharmaceuticals Inc. and the medicine "Soliris" Re: Schedule and Particulars of Allegations

We wish to re-confirm our understanding of the agreed-upon schedule and request further particulars and disclosure regarding the Statement of Allegations ("Statement").

Our understanding of the current schedule is:

1. Delivery of Alexion's Response to Statement of Allegations: 9 March 2015;

2. Delivery of Board Staff's Reply to the Response: 10 April 2015; and

3. Case Management Conference: No later than 30 April 2015.

The schedule is subject to any modifications that may be necessary as a result of interventions by provincial Attorneys General.

In our review of the Statement, we saw no details regarding Board Staff's analysis of the introductory price of Soliris, other than a bare mention that the Board recommended Soliris as a "breakthrough or substantial improvement" drug product when Alexion began selling Soliris in Canada at $224.7333/mL. Moreover, no mention is made in the Statement of the impact of foreign exchange rates on the outcome of the "Highest International Price Comparison test" Alexion's product is alleged to have failed.

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To fully appreciate and answer the claims in the Statement before delivering Alexion's Response, we would be grateful if you would provide the following particulars:

1. Any details concerning Board Staff's conclusions concerning the introductory price of Soliris; and

2. Board Staff's calculations concerning the impact of exchange rates on pricing of Soliris in the comparator countries listed in the Schedule to the *Patented Medicines Regulations*.

In addition, we request disclosure of any documents and/or records, such as notes, memoranda, or emails that illuminate or explain Board Staff's determinations concerning the introductory price and/or the impact of exchange rates under the Price Comparison test.

Please confirm the proposed schedule (subject to any modifications to accommodate provincial Attorneys General), and indicate when we can anticipate receiving a response to our other requests. We are hopeful that particulars and relevant documents can be delivered well in advance of the delivery date for Alexion's Response 9 March 2015.

Yours very sincerely,

GOWLING LAFLEUR HENDERSON LLP

Original signature redacted

Malcolm N. Ruby
MNR:gm:kam

TOR_LAW\ 8627475\2

APPENDIX B

PERLEY-ROBERTSON, HILL & McDOUGALL LLP/s.r.l.

Lawyers / Patent & Trade-Mark Agents
Avocats / Agents de brevets et de marques de commerce

Reply to/Communiquez avec:
David Migicovsky
613.566.2833 dmigicovsky@perlaw.ca

February 20, 2015

BY EMAIL

Malcolm N. Ruby
Gowling Lafleur Henderson LLP
100 King Street West, Suite 1600
Toronto, ON M5X 1G5

Dear Mr. Ruby:

Re: IN THE MATTER OF Alexion Pharmaceuticals Inc. and the medicine "Soliris"
Our Reference: PMPR010

This is further to your letter to Mr. Morris of February 12, 2015. The schedule set out in your letter is correct. That said, the Panel's order regarding scheduling does not reflect the agreed upon schedule. Consequently, Board Staff may request additional time to complete its reply if necessary.

In response to the request for particulars, Board Staff asserts that:

1. Alexion was previously provided with information related to the introductory price of Soliris. We refer you to Board Staff's letter to Alexion dated June 21, 2011, which is attached for your reference.

2. Board Staff conducted its calculations concerning the impact of exchange rates in accordance with the *Patented Medicines Regulations* and the 2010 Compendium of Guidelines, Policies and Procedures as Alexion is aware and as alleged in paragraph 15 of the Statement of Allegations.

It follows therefore that the particulars are within Alexion's knowledge. In any event, Alexion does not require these particulars to enable it to plead.

Finally, Alexion's request for documents is premature. Board Staff will deliver its documents within a reasonable timeframe after the parties have exchanged pleadings.

Yours very truly,

Original signature redacted

David Migicovsky
20: dem

c.c. Alan West; Parul Shah, Christopher P. Morris

AC, BM, CL(2)

Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

Box L40
Standard Life Centre
333 Laurier Avenue West
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Ottawa, Ontario
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PROTECTED – S. 87 PRIVILEGE

Via Facsimile: (905) 761-5289

094444

Our File #: 4100-A33-7 - Soliris

June 21, 2011

Mr. John Haslam
General Manager
Alexion Pharma Canada
Suite 120, 400 Applewood Crescent
Vaughan, Ontario
L4K 0C3

RE: Soliris 10 mg/mL (DIN 02322285)

Dear Mr. Haslam:

I am writing in regard to Board Staff's investigation into the price of Soliris 10 mg/mL (DIN 02322285) that was commenced June 25, 2010.

Board Staff has now reviewed all the information pertaining to Soliris and has accepted the company's amended Form 2, Block 5 data submitted by PDCI Market Access on behalf of Alexion Pharma on October 21, 2010 and on November 30, 2010. Based on the company's amended Form 2, Block 5 and Board Staff's Verification of International Prices, the price of Soliris 10 mg/mL no longer triggers the investigation criteria. There are, however, cumulative excess revenues remaining as of December 2010 of [redacted] A copy of Board Staff's analysis is attached for your information.

Alexion Pharma is being given the opportunity to take a voluntary price reduction to offset the cumulative excess revenues. To offset excess revenues via a price reduction, the average price will be considered to have been reduced if it is below the previous year's national non-excessive average price (N-NEAP). The current Guidelines state that excess revenue balances below the amount sufficient to trigger the investigation criteria that are carried for six consecutive six-month reporting periods (three years) will be expected to be offset through a Voluntary Compliance Undertaking (VCU). Alexion Pharma is expected to offset the outstanding [redacted] excess revenues by December 31, 2012 or it may be subject to a VCU for that amount.

.../2

If you have any questions or require further information in this regard, please do not hesitate to contact Anna Chodos at (613) 954-7654 or Béatrice Mullington at (613) 952-2924.

Yours truly,

Original signature redacted

Ginette Tognet
Director, Regulatory Affairs and
Outreach Branch

Attachment

THIS IS **EXHIBIT "K"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.

ALAN WEST

16 April 2015

Malcolm N. Ruby
Direct 416-862-4314
Direct Fax 416-863-3614
malcolm.ruby@gowlings.com
File No. T999663

VIA EMAIL and COURIER

Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa ON K1P 1C1

Attention: Mr. Guillaume Couillard, Secretary of the Board

Dear Mr. Couillard:

Re: Hearing into the Matter of Alexion Pharmaceuticals Inc. ("Alexion") and the medicine "Soliris"

Response to Amended Notice of Appearance of BC, MB, ON and NF, the Affidavit of Eric Lun, and Reply of Board Staff

We have now had the opportunity to review the B.C. Minister's Amended Notice of Appearance, the affidavit of Eric Lun, and Board Staff's Reply.

Alexion continues to assert that the issues raised in B.C.'s amended appearance and the Lun Affidavit are irrelevant to the proceeding being heard before the Board. The pertinent issues to be determined are described within Board Staff's Statement of Allegations and concern whether the price of Soliris is "excessive" based on subsection 85(1) of the *Patent Act* and, more particularly, the impact of fluctuating foreign exchange rates on medicines sold in Canada.

None of the facts stated or allegations made in the B.C. Minister's materials are relevant to the allegations made by Board Staff. Moreover, B.C.'s amended appearance requests application of a test—the "lowest price … among all comparator countries"— that cannot be found in either the *Patent Act* or the Board's Guidelines.

While we acknowledge that the provincial Ministers may attend the hearing and make representations under subsection 86(2) of the *Patent Act*, the representations must be "with respect to the matter being heard". The *Patent Act* does not confer a right to make submissions on irrelevant issues, much less the right to request an alternative remedy that goes beyond the *Act* and Guidelines.

gowlings

Finally, if the B.C. Minister's representations are considered, it will greatly complicate the nature of the evidence, the length of the hearing, and the costs to Alexion and all other parties.

Accordingly, at the upcoming first case conference, Alexion will seek procedural rulings from the Panel for:

1. A direction that Mr. Lun appear for cross-examination on his affidavit, that a transcript of the cross-examination be prepared, and that copies of the transcript be made available to the Board and the parties before the motion noted immediately below;

2. A direction establishing a schedule for a motion by Alexion for an order striking out irrelevant portions of the Amended Notice of Appearance;

3. An order compelling Board Staff to deliver particulars, and produce documents (including all notes, worksheets, etc.), relating to calculations used, made, or considered by Board Staff to determine the relevant international prices and foreign currency exchange rates upon which the allegations of excessive pricing are based; and

4. An order extending the date for Alexion to formally reply to the amended appearance until after the cross-examination is completed and the motion heard and decided.

We also wish to inform the Board that Alexion has instructed us to commence a proceeding before the Federal Court challenging the constitutional validity of *Patent Act* provisions underlying the Board's jurisdiction. Specifically, Alexion will be seeking a declaration that sections 83 through 86, and the words "in any proceedings under s. 83" in subsection 87(1) of the *Patent Act* are *ultra vires* because the provisions create a price control scheme outside Parliament's legislative authority. It is our intention to give notice of the constitutional challenge to all interested parties. We will be prepared to address any concerns about the constitutional challenge at the first case conference.

Yours very truly,

GOWLING LAFLEUR HENDERSON LLP

Original signature redacted

Malcolm N. Ruby

MNR:clh

gowlings

cc: VIA EMAIL:

Patented Medicine Prices Review Board
Legal Services Branch
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Attention: Ms. Parul Shah, Legal Counsel PMPRB

Perley-Robertson Hill & McDougal LLP
340 Albert Street
Suite 1400
Ottawa, ON K1R 7Y6

Attention: Messrs. David Migicovsky and Christopher Morris
Lawyers for Board Staff

Ministry of Justice
Legal Services Branch
PO Box 9280 STN PROV GOVT
1001 Douglas Street
Victoria, BC V8W 9J7

Attention: Ms. Sharna Kraitberg
Lawyer for Her Majesty the Queen in Right of the Province of British Columbia, as represented by the Minister of Health
Representative for the Interveners, the Provinces of Manitoba, Ontario, and Newfoundland and Labrador

Kapoor
Barristers
235 King Street East
2nd Floor
Toronto, ON M5A 1J9

Attention: Mr. Anil K. Kapoor
Lawyers for the Board

THIS IS **EXHIBIT "L"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.

ALAN WEST

PERLEY-ROBERTSON, HILL & McDOUGALL LLP/s.r.l.

Lawyers / Patent & Trade-Mark Agents
Avocats / Agents de brevets et de marques de commerce

Reply to/Communiquez avec:
David Migicovsky
613.566.2833 dmigicovsky@perlaw.ca

April 23, 2015

BY EMAIL

Mr. Guillaume Couillard
Secretary of the Board
Patented Medicine Prices Review Board
Legal Services Branch
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Mr. Malcolm Ruby/Mr. Alan West
Gowlings
1 First Canadian Place
100 King Street West, Suite 1600
Toronto, ON M5X 1G5

Dear Mr. Couillard and Counsel:

Re: Alexion Pharmaceuticals Inc. and the medicine "Soliris"
Our Reference: PMPR010

We are writing in response to Mr. Ruby's letter of April 16, 2015.

Board Staff does not agree with Alexion's assertion that the issue can be described as relating to "… the impact of fluctuating foreign exchange rates on medicines sold in Canada." As alleged in Board Staff's Statement of Allegations and affirmed in its Reply, Board Staff have not alleged that the price of Soliris is excessive because of foreign exchange rates. Rather, Board Staff alleges that based on the factors under section 85 of the *Patent Act* (the "*Act*"), Alexion has been selling Soliris at a price that is excessive since 2012.

We further note that we are not in agreement with the assertion made by Mr. Ruby that the facts and allegations made in the B.C. Minister's materials are not relevant. Board Staff submits that B.C. is entitled to appear and make representations with respect to the matter being heard; namely, whether the price of Soliris is excessive.

Mr. Ruby indicates his intention of seeking procedural rulings from the Panel at the upcoming first Case Management Conference. We note, however, that Rule 22 of the *Patented Medicine Prices Review Board Rules of Practice and Procedure* ("the *Rules of Practice and Procedure*") circumscribe the purposes of the Case Management Conference. Accordingly, we do not agree that Alexion is entitled to seek the procedural rulings set out in Mr. Ruby's correspondence at the Case Management Conference. It would, however, be appropriate to consider fixing a schedule and identifying any issues to be resolved at the Case Management Conference. In the event Mr. Ruby intends to bring various motions, then we suggest a schedule for such motions and the delivery of motion materials be addressed at the Case Management Conference. The motions themselves should then be heard during the Pre-Hearing Conference under Rule 23 of the *Rules of Practice and Procedure*.

We further note that Alexion intends to seek an order compelling Board Staff to deliver particulars to enable it to plead. Given that Alexion has already filed a Response, such a request would now appear to be moot. In any event, should Alexion decide to seek an order for particulars, the matter should be dealt with in accordance with the procedure set out above, which also requires Alexion to file a Motion Record.

We note that Alexion now intends to commence a constitutional challenge in Federal Court challenging the constitutional validity of the *Patent Act* provisions underlying the Board's jurisdiction. Alexion did not, however, raise any constitutional challenge in its Response. In our submission, the appropriate venue for Alexion to institute this challenge would be before the Panel hearing this case.

Yours very truly,

Original signature redacted

David Migicovsky
20:llc
cc Christopher Morris (by email)
Parul Shah (by email)
Sharna Kraitberg (by email)

THIS IS **EXHIBIT "M"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.

ALAN WEST

27 April 2015

Malcolm N. Ruby
Direct 416-862-4314
Direct Fax 416-863-3614
malcolm.ruby@gowlings.com
File No. T999663

VIA EMAIL and COURIER

Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa ON K1P 1C1

Attention: Mr. Guillaume Couillard, Secretary of the Board

Dear Mr. Couillard:

Re: Hearing into the Matter of Alexion Pharmaceuticals Inc. ("Alexion") and the medicine "Soliris"

Response to Letter From D. Migicovsky – Perley-Robertson (23 April 2015)

Mr. Migicovsky's 23 April 2015 letter is deeply troubling.

The letter demonstrates, yet again, Board Staff's refusal to provide sufficient details to support the allegation that the price of Soliris was excessive in 2012 and 2013. Alexion is entitled, as is any respondent to a proceeding prosecuted before the Board (or similar proceedings) to particulars of the case they are asked to meet. It is our intention to raise this most serious and fundamental procedural unfairness immediately at the outset of the case management conference to be held this week. We believe Board Staff's refusal to provide particulars, combined with their recent case theory shift, borders on prosecutorial misconduct because of the apparently deliberate failure to disclose details about the case that are vital to both Alexion and the Panel's ability to understand the case.

In *Fischer v. Canada (Attorney General)*, [2012] F.C.J. No. 793 (FTD) at paragraph 27, the Federal Court affirmed the right of a party to an administrative proceeding to know the case to be met so that the party can prepare and respond in a meaningful way. This right to know that case to be met has been characterized as a principle of fundamental justice: *audi alteram partem*.

In the *criminal* context, the Supreme Court's decision in *R v Stinchcombe*, [1991] 3 S.C.R. 326 (SCC) has long been cited for the proposition that the Crown has a duty to provide the defence with all evidence that could possibly be relevant to the case, regardless of whether

or not the Crown plans to call that evidence at trial, or whether it helps or hurts the Crown's case. While the *Stinchcombe* standards are reserved for criminal cases, recent Supreme Court jurisprudence holds that in the administrative context procedural fairness generally requires disclosure of information relied upon in the prosecution of administrative cases. In *May v. Ferndale Institution,* [2005] 3 S.C.R. 809 (SCC) at paragraphs 92 and 93, the majority described the duty of disclosure as follows:

> 92 In the administrative context, the duty of procedural fairness generally requires that the decision-maker discloses the information he or she relied upon. The requirement is that the individual must know the case he or she has to meet. If the decision-maker fails to provide sufficient information, his or her decision is void for lack of jurisdiction. As Arbour J. held in Ruby, at para. 40:
>
> > As a general rule, a fair hearing must include an opportunity for the parties to know the opposing party's case so that they may address evidence prejudicial to their case and bring evidence to prove their position ... .
>
> 93 Therefore, the fact that *Stinchcombe* does not apply does not mean that the respondents have met their disclosure obligations.

Without the requested particulars, it is not possible for Alexion to respond to the topics in the agenda proposed in the "Directive to Parties regarding Case Management Conference" delivered to us on 21 April 2014. We cannot, for example, make submissions on fixing hearing dates, the evidence to be filed, or the expected duration of the hearing when we do not even know the allegations against Alexion—other than the repeated bald assertion of Board Staff and their counsel that "based on the factors under section 85 of the *Patent Act*, Alexion has been selling Soliris at a price that is excessive since 2012." This allegation is meaningless without details of <u>how</u> the medicine is over-priced and what "factors" Board Staff rely upon given that the price of Soliris has not increased since the product was first introduced on the Canadian market in 2009.

Despite the inexplicable refusal of Board Staff, and their counsel, to provide particulars of how they arrived at their conclusion of "excessive" pricing, we have previously stated our understanding that Board Staff's case was based on an alleged failure of Soliris to meet Board Staff's application of the so-called Highest International Price Comparison (or HIPC) test based on changes in valuation of the Canadian dollar *vis a vis* foreign currencies in the relevant foreign jurisdictions where Soliris is sold. Our understanding is, in part, based on assumptions because despite our repeated requests, we have never been provided:

(a) details of how Board Staff applied the HIPC test;

(b) copies of Board Staff's worksheets, spreadsheets, and calculations; or

(c) any other specifics of how the price of Soliris allegedly failed to pass the HIPC test.

Our requests have been met with absurd assertions that Alexion already has this information, which is patently false. Moreover, we were astonished to learn from Board Staff counsel's recent letter to you that they appear have shifted away from the position advanced in the Statement of Allegations that the price of Soliris was excessive based on foreign currency exchange rates and the HIPC test (see second paragraph of counsel's 23 April letter).

The procedurally unfair tactics Board Staff are using in the prosecution of this case against Alexion amount, in effect, to deliberate non-disclosure designed to frustrate Alexion's ability to understand the case to be met. Moreover, Board Staff have recently began to rely upon a vague, unsubstantiated, and shifting case theory. This approach is neither fair nor proper. It is not how any litigation should be conducted, let alone a prosecution by a public authority purportedly acting in the public interest.

Alexion delivered a Response to the Statement of Allegations on 9 March 2015. In paragraph 10 of the Response, attention was drawn to Board Staff's failure to provide sufficient particulars for Alexion to fully plead. Indeed, Alexion reserved its right to amend the Response once particulars were provided or ordered. We have repeatedly asked counsel for particulars and in our 16 April letter we clearly communicated that at the first case conference procedural rulings would be sought concerning, among other topics, an order compelling Board Staff to deliver particulars including the documents specified in our letter. We categorically reject Board Staff counsel's assertion that because Alexion has already filed a Response, its request for particulars is moot. This type of submission is inconsistent with Board Staff's obligation to proceed fairly and responsibly in the public interest.

Alexion's concerns about this continuing unfairness was compounded by the recent Directive from the Board—which makes no mention of the request for the procedural directions we seek. Instead, the Directive methodically lists topics the Board Panel wish to canvass without apparent regard for the concern raised by Alexion from the beginning that it cannot sensibly deal with the case, or agree to further procedural steps, until provided with sufficient information to properly respond.

Alexion has retained an expert witness to deal with the HIPC test and fluctuations in foreign currency exchange rates. Alexion is not prepared to deal with other allegations because we do not know what the allegations are. We therefore cannot know whether we require another expert witness, or even a 'fact' witness to respond to allegations that do not state any sensible or comprehensible case theory. Stated bluntly, we cannot make any meaningful assessment of the next procedural steps for a hearing while Board Staff stubbornly refuse to tell us what the case is about. Without knowing what the case is about, we cannot make any informed assessment about how the hearing will proceed, let alone how long it should last or what the evidence will be.

Board Staff's obdurate refusal to provide particulars leads us to suspect that Board Staff, or their counsel, are incapable of asserting any intelligible case, other than repeating the mantra that the price of Soliris is "excessive" because it is expensive. This is a conclusion and not a reasoned position based on the *Patent Act* or the Guidelines.

With respect to the intervention of the provincial ministers, other than the suggestion that the ministers "rely upon the material facts set out in the Statement of Allegations, and upon the documents noted in the List of Attachments to the Statement of Allegations", nothing they allege, state, assert, or rely upon is at all relevant to the case stated in the Statement of Allegations. As indicated in our 16 April letter, we will seek procedural directions at the case conference for a motion before the Panel to strike the irrelevant portions of the Ministers' Amended Notice of Appearance. For the same reasons stated above, before the motion concerning the Ministers' allegations is dealt with, we cannot estimate the number of days a hearing may take, fix a schedule, or ascertain what evidence will be called by Alexion.

It would be inappropriate to impose a schedule on Alexion before the nature of Board Staff's case is made clear and the appropriateness of the Ministers' allegations is determined. Alexion must know the case it has to meet before it can deliver a complete response or marshal the evidence necessary to meet the allegations. We believe it is premature to deal with scheduling until these preliminary issues are resolved.

We also believe, with respect, that the appropriate forum for the constitutional challenge based on division of powers is before the Federal Court. The Board's expertise is based on pricing of particular medicines and not on whether Parliament has legislative authority to direct the Board to engage in that process in the first place. Moreover, assuming Alexion is properly made aware of the case it has to meet and the Panel deals appropriately with the Ministers' allegations, Alexion has no intention to delay the proceedings while the constitutional challenge proceeds before the Federal Court. In our letter, we were being open and transparent in disclosing to the Panel that the Federal Court proceeding will be brought. We were hoping that Board Staff would be similarly transparent and open in relation to the nature of their case against Alexion but have been significantly disappointed thus far.

Apart from requesting that the English language be used, until we know the case Alexion has to meet, it is not possible for us to make written submissions on documentary productions, witnesses, experts, or "expected duration of the pleadings." For purposes of the case conference, we are asking the Panel to order Board Staff to deal with the "Other Issues" posed in our 16 April letter and this correspondence.

Finally, we are willing to participate in an appearance before the Panel if it would facilitate the resolution of these preliminary issues and enable the parties and the Panel to address all issues in the recent Directive.

gowlings

Yours very truly,

GOWLING LAFLEUR HENDERSON LLP

Original signature redacted

Malcolm N. Ruby
MNR:kam

cc: Via E-Mail

Patented Medicine Prices Review Board
Legal Services Branch
Standard Life Centre
Suite 1400
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Attention: Ms. Parul Shah, Legal Counsel PMPRB

Perley-Robertson Hill & McDougal LLP
340 Albert Street
Suite 1400
Ottawa, Ontario
K1R 7Y6

Attention: Messrs. David Migicovsky and **Christopher Morris**
Lawyers for Board Staff

Ministry of Justice
Legal Services Branch
PO Box 9280 STN PROV GOVT
1001 Douglas Street
Victoria, BC V8W 9J7

Attention: Ms. Sharna Kraitberg
Lawyer for Her Majesty the Queen in Right of the Province of British Columbia, as represented by the Minister of Health Representative for the Interveners, the Provinces of Manitoba, Ontario, and Newfoundland and Labrador

gowlings

Kapoor Barristers
235 King Street East
2nd Floor
Toronto, Ontario
M5A 1J9

Attention: Mr. Anil K. Kapoor
Lawyers for the Board

TOR_LAW\ 8682199\4

THIS IS **EXHIBIT "N"** TO THE AFFIDAVIT
OF **ANNA DI DOMENICO** SWORN BEFORE
ME THIS 15TH DAY OF MAY, 2015

Original signature redacted

A Commissioner etc.

ALAN WEST

IN THE MATTER OF the Patent Act R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. (the "Respondent") and the medicine "Soliris"

ORDER REGARDING SCHEDULING OF THE PRE-HEARING CONFERENCE AND CROSS-EXAMINATION ON THE AFFIDAVITS

Decided by the Hearing Panel on the basis of the Case Management Conference and associated written and oral submissions made by the Parties.
Date of Order: May 1, 2015

1. FURTHER to the Case Management Conference of April 29, 2015 and associated written and oral submissions made by the Parties.

THE BOARD ORDERS THAT:

1. The Pre-Hearing Conference, under section 23 of the Patented Medicine Prices Review Board Rules of Practice and Procedure (the Rules), be in-person, in Ottawa on June 22, 23 and 24, 2015.

2. Parties seeking relief from the Panel pursuant to Rule 25 must serve and file their application materials, in accordance with section 10 of the Rules, by 5:00 pm (Eastern Time) on May 15, 2015.

3. Responding materials must be filed, in accordance with section 10 of the Rules, by 5:00 pm (Eastern Time) on May 29, 2015.

4. Any Reply materials must be filed, in accordance with section 10 of the Rules, by 5:00 pm (Eastern Time), on June 5, 2015.

5. The Parties are granted leave to cross-examine on any affidavits filed in accordance with section 25 of the Rules, and that transcripts of the cross-examinations be served on all Parties and filed with the Board by 5:00 pm (Eastern Time) on June 17, 2015. For greater clarity, this provision does not apply to the affidavit of Mr. Lun as the cross-examination of Mr. Lun is one of the issues that will be dealt with at the Pre-Hearing Conference.

DATED at Ottawa, this 1st day of May, 2015

Original signed by

Signed on behalf of the Board by
Dr. Mitchell Levine

COUNSEL / REPRESENTATIVES:

For Board Staff:

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